

## SENT VIA EMAIL

Connie Karr Oregon Tilth Certified Organic 260 SW Madison Ave., Suite 106 Corvallis, OR 97333 connie@tilth.org

Re: NOPC-053-12 Organic Avenue

Dear Ms. Karr:

The U.S. Department of Agriculture, National Organic Program (NOP) has concluded its investigation of a complaint filed regarding your client, Organic Avenue in December 2011. The complaint alleged that Organic Avenue represented itself as an organic operation without certification in violation of the NOP regulations.

Our investigation found that Organic Avenue was in the process of completing handler certification from Oregon Tilth Certified Organic, Inc. shortly after the complaint was filed. Our investigation also confirmed the allegations identified in the complaint. Until recently, Organic Avenue represented itself as an organic operation from 2004 – 2012, in violation of the regulations.

Inasmuch as Organic Avenue has taken action to achieve compliance with the NOP regulations, we are closing the investigation.

As always, we appreciate your support of the NOP and the USDA.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program

cc: Director, Accreditation & International Activities Division



## CASE CLOSURE MEMORANDUM

- TO: Matthew Michael Director NOP Compliance and Enforcement Division (C&E)
- FROM: Tammie Wilburn Agricultural Marketing Specialist NOP Compliance and Enforcement Division (C&E)
- SUBJECT: NOPC-053-12 Organic Avenue Long Island City, New York

## CERTIFYING AGENTS INVOLVED:

## COMPLAINANT:

(b)(6),(b)(7)(c),(b)(7)(d)

## ALLEGED VIOLATION: 7 CFR 205.100

(b)(6).(b)(7)(c).(b)(7)(d) alleges that Organic Avenue, New York, NY, is representing for on-line and retail sale a variety of juice and cleanse products as "all organic" and "entirely organic." The complainant provided links to the operator's website that makes the product claims.

## SUMMARY:

C&E reviewed Organic Avenue's website, <u>http://www.organicavenue.com/about.php</u> and found several marketing claims consistent with the allegations being made. The majority of Organic Avenue's products are packaged in glass bottles with the "Organic Avenue" trade name displayed on the principle display panel. Organic Avenue is not on the NOP's Certified Operations list. While not conclusive, our investigation identified the following violations of the NOP regulations:

- 1. The use of the trade name "Organic Avenue,"
- 2. Labeling water as organic,
- 3. Labeling salt as organic,
- 4. Retail sales at Organic Avenue's store locations
- 5. Website sales of products represented as organic at <u>www.organicavenue.com</u>,

- 6. Website marketing of products represented as organic at <u>www.facebook.com</u> and <u>www.twitter.com</u>, and,
- 7. Home delivery and sales of products represented as organic.

## June 2012

C&E issued a Cease and Desist letter to Organic Avenue and requested a written response within 10 business days.

## July 2012

C&E received a response from Organic Avenue's Chief Executive Officer, Douglas Evans. Mr. Evans responded that Organic Avenue was established in the year 2000, prior to NOP's existence. He stated that in May of this year (2012), Organic Avenue initiated and received organic handler certification from Oregon Tilth, Inc. Mr. Evans also stated that OTCO was still in the process of approving several formulations and labels but that the company was indeed certified organic.

Connie Karr with OTCO notified C&E via email and confirmed that OTCO certified Organic Avenue on May 23, 2012 after a full facility inspection on May 1, 2012 (Exhibit 2). Connie also noted that although certified, not any of Organic Avenue's products labels were yet listed and approved by OTCO. Connie finally stated that Organic Avenue was reminded that no products were approved in their certification decision letter that was sent along with the certification.

C&E's investigation subsequently found that Organic Avenue began representing its agricultural products as organic as far back as 2004, without certification, in violation of the regulations.

## ACTION REQUESTED:

C&E recommends that NOPC-053-12 be closed with a Notice of Civil Penalty for \$8,000 with Settlement Agreement to Organic Avenue. The \$8,000 represents \$1,000 reduced civil penalty for 8 years of violating. A Notice of Civil Penalty, Settlement Agreement, and Closure letters to the complainant and certifying agent are attached for review and approval.



Denise Mari, Owner Organic Avenue/ The Space of LOVE 115 Suffolk Street New York, New York 10002

Re: NOPC-053-12 Organic Avenue

## NOTICE TO CEASE AND DESIST

Dear Ms. Mari:

The U.S. Department of Agriculture National Organic Program (NOP) enforces the Organic Foods Production Act (OFPA) of 1990, as amended, and its implementing regulations in 7 CFR 205. The NOP regulations at 7 CFR 205.100(a) require that except for operations exempt or excluded, all production and handling operations that sell, label or represent agricultural products as "100% organic, "organic" or "made with organic" ingredients be certified by a USDA-accredited certifying agent and comply with the NOP regulations. Our regulations can be found at www.ams.usda.gov/nop.

The NOP received a complaint alleging that Organic Avenue is in violation of the NOP regulations by selling, labeling and representing its products as "100% organic" and "organic" without certification. The complaint specifically references statements made on the Organic Avenue website claiming that all of Organic Avenue's products are organic. Our initial investigation into the complaint finds that Organic Avenue's product labels and marketing information violate the OFPA and the NOP regulations in numerous instances. The violations fall into two categories:

1. At numerous locations on the Organic Avenue website (<u>www.organicavenue.com</u>) you claim that Organic Avenue products are organic. For example, on your "FAQ" page (<u>https://www.organicavenue.com/why\_love\_faq.php#are-all-products-organic</u>) the following text is presented:

Are your products all organic? Yes! Every ingredient is 100% organic always and local when possible. In addition to buying certified organic produce, we love supporting small farmers who use organic methods yet can't afford USDA certification. We also purchase wild, unsprayed produce, like our delicious Thai coconuts.

As stated above, similar violations occur elsewhere on your website, either as general statements or in descriptions of specific products. Organic Avenue products may not be sold, labeled or represented as "organic" because they are not produced and handled in accordance with the requirements of the OFPA and the NOP regulations.

2. The use of the trade name "Organic Avenue" on the principal display panel of the labeling of numerous of your products falsely implies that those products are produced and handled in compliance with the OFPA and the NOP regulations. The OFPA, under 7 USC 6505(a)(1)(B), requires that "no person may affix a label to, or provide other market information concerning, an agricultural product if such label or information implies, directly or indirectly, that such product is produced and handled using organic methods, except in accordance with this chapter." Organic Avenue may not use this trade name to imply that its products are produced and handled in accordance with the NOP regulations.

Be advised that Organic Avenue must immediately **CEASE AND DESIST** violation of the requirements in the OFPA and the NOP regulations. Failure to take action in this matter may result civil penalties of \$11,000 for each violation identified.

Within 10 business days of receipt of this letter, please notify the NOP in writing of your plan to come into compliance with the regulations. You may submit your written response to Tammie Wilburn, Compliance Specialist, at <u>Tammie.Wilburn@ams.usda.gov</u>. Ms. Wilburn can also be reached at (202) 720-3252.

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division National Organic Program





Denise Mari, Owner Organic Avenue/ The Space of LOVE 115 Suffolk Street New York, New York 10002

Re: NOPC-053-12 Organic Avenue

## NOTICE TO CEASE AND DESIST

Dear Ms. Mari:

The U.S. Department of Agriculture National Organic Program (NOP) enforces the Organic Foods Production Act of 1990, as amended, and its implementing regulations (7 CFR 205). The NOP regulations require that all production and handling operations that sell, label or represent agricultural products as "organic" be certified by a USDA-accredited certifying agent and comply with the NOP regulations. Our regulations can be found at <u>www.ams.usda.gov/nop</u>.

The NOP has received a complaint alleging that Organic Avenue is in violation of 7 CFR 205. The complaint specifically references statements made at <u>www.organicavenue.com</u> and the claim that all of Organic Avenue's products are organic (Enclosure 1). Our initial investigation into the complaint found that, unless exempt or certified organic, Organic Avenue's statement, product labels and marketing practices violate 7 CFR 205. While not conclusive, our investigation also identified other violations of the regulations. They include:

- 1. The use of the trade name "Organic Avenue,"
- 2. Labeling water as organic,
- 3. Labeling salt as organic,
- 4. Retail sales at Organic Avenue's store locations
- 5. Website sales of products represented as organic at <u>www.organicavenue.com</u>,
- 6. Website marketing of products represented as organic at <u>www.facebook.com</u> and <u>www.twitter.com</u>, and
- 7. Home delivery and sales of products represented as organic.

This is to advise that Organic Avenue must immediately **CEASE AND DESIST** violation of 7 CFR 205. Failure to take action in this matter may result in further investigation and potential legal action including civil penalties of \$11,000 for each violation identified.

NOPC-053-12 Organic Avenue Page 2

Please respond to this notice in writing within <u>7 days</u> of receipt of this letter. You may submit your written response to Tammie Wilburn, Compliance Specialist, at <u>Tammie.Wilburn@ams.usda.gov</u>. Ms. Wilburn can also be reached at (202) 720-3252.

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division National Organic Program



## **Check Transmittal Memo**

- To: Lavern Harris Resource Management Branch Compliance & Analysis Agricultural Marketing Service
- From: Tammie Wilburn Compliance and Enforcement National Organic Program Agricultural Marketing Service
- **Date:** October 23, 2012
- **Re:** Organic Avenue NOPC-053-12 Settlement Agreement Payment

Enclosed is a (b)(4) . check(b) (4) from Organic Avenue LLC in the amount of \$4,000. This payment is one of two toward the \$8,000 civil penalty agreed to under a settlement agreement between Organic Avenue and the USDA National Organic Program.



SENT VIA EMAIL

Douglas Evans Chief Executive Officer Organic Avenue 43-47 9<sup>th</sup> Street Long Island Citgy, New York 11101 dougevans@organicavenue.com

Re: NOPC-053-12 Organic Avenue

Dear Mr. Evans:

The U.S. Department of Agriculture National Organic Program (NOP) has concluded its investigation of a complaint filed against Organic Avenue. The complaint alleged that Organic Avenue marketed and sold its coffee products as "organic" in violation of the NOP regulations, 7 CFR 205.

Our investigation confirmed this allegation, however, Organic Avenue has taken action to achieve compliance with the NOP regulations and has since completed organic certification from Oregon Tilth Certified Organic. Organic Avenue also settled the violation through payment of a reduced civil penalty under settlement agreement (signed agreement enclosed).

This communication closes our files on this matter. Thank you for your cooperation during the investigation of this complaint.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program



SENT VIA EMAIL

SEP 24 2012

Connie Karr Oregon Tilth Certified Organic 260 SW Madison Ave., Suite 106 Corvallis, OR 97333 connie@tilth.org

Re: NOPC-053-12 Organic Avenue

Dear Ms. Karr:

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Our investigation found that Organic Avenue was in the process of completing handler certification from Oregon Tilth Certified Organic, Inc. shortly after the complaint was filed. Our investigation also confirmed the allegations identified in the complaint. Until recently, Organic Avenue represented itself as an organic operation from 2004 – 2012, in violation of the regulations.

Inasmuch as Organic Avenue has taken action to achieve compliance with the NOP regulations, we are closing the investigation.

As always, we appreciate your support of the NOP and the USDA.

Sincerely,

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Miles V. McEvoy Deputy Administrator National Organic Program

cc: Director, Accreditation & International Activities Division



SENT VIA EMAIL

)(6),(b)(7)(c),(b)(7)(d)	
Re: NOPC-053-12 Organic Avenue	

SFP 24 2012

Dear

The U.S. Department of Agriculture (USDA), National Organic Program (NOP) has concluded its investigation of the complaint you filed against Organic Avenue of New York, New York (Organic Avenue), in December 2011. Your complaint alleged that Organic Avenue represents itself as an organic operation without certification in violation of the NOP regulations.

Our investigation confirmed the allegation. The investigation also found that Organic Avenue recently completed handler certification from Oregon Tilth Certified Organic, Inc. Nonetheless, as a result of our investigation, NOP has issued Organic Avenue a Notice of Civil Penalty for violations of the regulations prior to acquiring organic status.

Thank you for bringing this matter to our attention. We appreciate your support of the NOP and the USDA.

Sincerely,

Tudor Formum

Miles McEvoy Deputy Administrator National Organic Program



SENT VIA EMAIL



Re: NOPC-053-12 Organic Avenue

(b)(6),(b)(7)(c),Dear(b)(7)(d)

The U.S. Department of Agriculture (USDA), National Organic Program (NOP) has concluded its investigation of the complaint you filed against Organic Avenue of New York, New York (Organic Avenue), in December 2011. Your complaint alleged that Organic Avenue represents itself as an organic operation without certification in violation of the NOP regulations.

Our investigation confirmed the allegation. The investigation also found that Organic Avenue recently completed handler certification from Oregon Tilth Certified Organic, Inc. Nonetheless, as a result of our investigation, NOP has issued Organic Avenue a Notice of Civil Penalty for violations of the regulations prior to acquiring organic status.

Thank you for bringing this matter to our attention. We appreciate your support of the NOP and the USDA.

Sincerely,

Miles McEvoy Deputy Administrator National Organic Program

# Complaint Investigation Chronology Log

# Case #: NOPC-053-12 Subject: Organic Avenue Compliance Specialist:WILBURN

Date	Activity
12/12/11	C&E received a complaint from (b)(6)(b)(7)(c) regarding Organic Avenue,, New York, New York. (b)(6),(b)(7)(c),(b)(7)(d) alleged that Organic Avenue is representing for on-line and retail sale a variety of juice and cleanse products as "all organic" and "entirely organic." (b)(6),(b)(7)(c), provided links to the operator's website, The products are packaged in glass bottles with the "Organic Avenue" trade name displayed on the principle display panel. Organic Avenue is not on the NOP's Certified Operations list. (http://www.organicavenue.com/about.php)
3/14/12	Cease and Desist letter to Organic Avenue was sent forward for review and signature
4/23/12	Received approval to issue C&D letter with discussion first
6/26/12	Cease and Desist issued to Organic Avenue
6/27/12	C&E received a response from Organic Avenue's CEO, Douglas Evans. Mr. Evans Mr. Evans responded that Organic Avenue was established in the year 2000, prior to NOP's existence. He stated that in May of this year (2012), Organic Avenue initiated and received organic handler certification from Oregon Tilth, Inc. Mr. Evans also stated that OTCO was still in the process of approving several formulations and labels but that the company was indeed certified organic. Mr. Evan's response referenced a copy of the certificate; however, no certificate was attached.
7/9/12	C&E contacted OTCO to confirm certication
7/10/12	Connie Karr with OTCO notified C&E via email and confirmed that OTCO certified Organic Avenue on May 23, 2012 after a full facility inspection on May 1, 2012 Connie also noted that although certified, not any of Organic Avenue's products labels were yet listed and approved by OTCO. Connie finally stated that Organic Avenue was reminded that no products were approved in their certification decision letter that was sent along with the certification. Connie provided a copy of OTCO's certification.
8/1/12	Case reviewed and submitted for closure.

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Date: Author:	October 14, 2012 T. Wilburn			
File Location:	(b)(7)(e)			
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Compliance and	Enforcement Director	Initials:	Matthew Michael	
			Initials and Date	
Remarks:				
Final:	Approved	Further Ed	liting Required	
Deputy Adminis	strator Initials: Miles	<b>V. McEvoy</b> ad Date		
Remarks:				

# Return to: C&E Director

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From:	AMS - NOPCompliance
То:	Tucker, Jennifer - AMS
Subject:	Incoming complaint (non-certified): Organic Avenue juices
Date:	Monday, December 12, 2011 11:38:00 AM

Jenny-

Below is a prospective complaint submitted to the NOP Compliance inbox by (b)(6).(b)(7)(c),(b) The complaint alleges that Organic Avenue, New York, NY, is representing for on-line and retail sale a variety of juice and cleanse products as "all organic" and "entirely organic." The complainant provided links to the operator's website that makes the product claims. The products are packaged in glass bottles with the "Organic Avenue" trade name prominently displayed on the principle display panel. Organic Avenue is not on the NOP's Certified Operations list.

Thank you. Kristin

#### From: (b)(6),(b)(7)(c),(b)(7)(d)

Sent: Monday, December 12, 2011 10:36 AM To: AMS - NOPCompliance Subject: Organic Avenue juices

NOP Compliance & Enforcement,

A juice company based in NYC called Organic Avenue has been making organic claims, as you can see from their website q&a section (<u>http://www.organicavenue.com/why\_love\_faq.php#are-all-products-organic</u>): " 'Are your products all organic?'

'Yes! Every ingredient is 100% organic always and local when possible. In addition to buying certified organic produce, we love supporting small farmers who use organic methods yet can't afford USDA certification. We also purchase wild, unsprayed produce, like our delicious Thai coconuts.' "

In their "about me" section, they claim: "*Our juice is made and delivered fresh daily, bottled in glass (or, when shipping, bio-plastic, which is non-toxic to people and to the environment) and is entirely organic.*" (http://www.organicavenue.com/about.php)

I have not been able to find a certifier statement anywhere for them to be making these claims of their products.

Their main location appears to be The Space of LOVE\* 116 Suffolk Street, (between Rivington & Delancey) New York, NY 10002. Their contact number is 212-358-0500.

Thank you for looking into this.



(b)(6),	
(b)(7)	
(c),(b)	
(7)(d)	



#### NOTICE OF CIVIL PENALTY

Douglas Evans Chief Executive Officer Organic Avenue 43-47 9<sup>th</sup> Street Long Island City, New York 11101 dougevans@organicavenue.com

Re: NOPC-053-12 Organic Avenue

Dear Mr. Evans:

The U.S. Department of Agriculture (USDA) National Organic Program (NOP) implements the Organic Foods Production Act of 1990 (OFPA) and its implementing regulations under 7 CFR Part 205. All agricultural products sold, labeled or represented as organic must be certified by a USDA-accredited certifying agent (ACA) and produced and handled in compliance with the USDA organic regulations.

As you know, in 2011 the NOP received a complaint alleging that Organic Avenue violated the NOP regulations by selling, labeling and representing its products as "100% organic" and "organic" without certification. Our investigation into the complaint found numerous claims at <u>www.organicavenue.com</u> to substantiate this allegation. We also found that your products were labeled and misrepresented as organic by use of the trade name "Organic Avenue."

As a result of our initial findings, on June 25, 2012, the NOP issued Organic Avenue a Notice to Cease and Desist (Notice) violating of OFPA and the NOP regulations. In response to the Notice, you agreed to update your website to comply with the regulations. You also advised that effective May 2012, Organic Avenue had achieved organic certification for handling from Oregon Tilth Certified Organic (OTCO). In later communication with OTCO, we were informed that OTCO issued Organic Avenue certification based on a full facility inspection only, and that no products or labels have yet been listed or approved for organic representation. Nonetheless, Organic Avenue continues to sell its products, labeled as "organic," without the labels having been approved by OTCO.

Finally, further investigation into the complaint found information dating back to at least the year 2004, a timeframe of 8 years, where Organic Avenue has misrepresented either itself or its agricultural products as organic, without certification, via product labeling and market information on the Internet, in violation of OFPA and the USDA organic regulations.



The aforementioned findings are in direct violation of the regulations. Paragraph 205.100(c) of the 7 CFR 205 states that *any operation that knowingly sells or labels a product as organic, except in accordance with OFPA, shall be subject to a civil penalty of not more than \$11,000 per violation.* Based on the evidence of this case, the NOP could pursue this matter by requesting a formal administrative proceeding and filing a complaint alleging the above referenced violations. If filed, the case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Given the continuing violations concerning product labeling and number of years (8) in violation of the USDA organic regulations, the civil penalties levied against Organic Avenue in this case could far exceed \$11,000.

As an alternative to a formal administrative proceeding and to resolve this matter, the NOP is offering the attached settlement agreement, which includes a reduced civil penalty of \$8,000 and an agreement by Organic Avenue to immediately comply with the USDA organic regulations. Please note that your cooperation and recent certification were considered in calculating the reduced settlement amount offered by the USDA. Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. Please sign the original and return it to the address noted below by **October 26, 2012**, along with a \$4,000 certified check or money order made payable to the "Treasurer of the United States." The remaining \$4,000 should be paid by **December 3, 2012**. Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave., SW Room 2646-S, STOP Code 0268 Washington, D.C. 20250-0268 Attn: Tammie Wilburn

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If you have any questions regarding this notice, please contact Ms. Wilburn at <u>tammie.wilburn@ams.usda.gov</u> or 202-260-8638.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program

Enclosure - settlement agreement for signature

cc: Connie Karr, OTCO (CCOF)

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## NOTICE OF CIVIL PENALTY

Douglas Evans Chief Executive Officer Organic Avenue 43-47 9<sup>th</sup> Street Long Island City, New York 11101 dougevans@organicavenue.com

Re: (b)(5)

Dear Mr. Evans:

The U.S. Department of Agriculture (USDA) National Organic Program (NOP) implements the Organic Foods Production Act of 1990 (OFPA) that requires all agricultural products sold, labeled or represented as organic be certified by a USDA-accredited certifying agent (ACA) and produced and handled in compliance with the NOP regulations, 7 CFR Part 205.

As you know, in 2011 the NOP received a complaint alleging that Organic Avenue violated the NOP regulations by selling, labeling and representing its products as "100% organic" and "organic" without certification. Our investigation into the complaint found several claims at <u>www.organicavenue.com</u> to substantiate this allegation. We also found that many of your products were labeled and misrepresented as organic by use of the trade name "Organic Avenue."

As a result of our initial findings, on June 25, 2012, the NOP issued Organic Avenue a Notice to Cease and Desist (Notice) violation of OFPA and the NOP regulations. In response to the Notice, you agreed to update your website to comply with the regulations. You also advised that effective May 2012, Organic Avenue achieved organic certification for handling from Oregon Tilth Certified Organic (OTCO). In later communication with OTCO, we were informed that OTCO advised Organic Avenue that its certification had been issued based on a full facility inspection, but no products or labels had yet been listed or approved for organic representation.

Finally, further investigation into the complaint found information dating back to at least the year 2004, a timeframe of 8 years, where Organic Avenue has misrepresented either itself or its agricultural products as organic, without certification, in violation of OFPA and the NOP regulations.

The aforementioned findings are in direct violation the regulations. Paragraph 205.100(c) of the 7 CFR 205 states that *any operation that knowingly sells or labels a product as organic, except in accordance with OFPA, shall be subject to a civil penalty of not more than \$11,000 per violation*. Based on the evidence of this case, the NOP retains the right to pursue this matter formally by requesting a formal administrative proceeding and filing a complaint alleging the



above referenced violations. If filed, the case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. In this matter, given the recent violations and number of years (8) in violation, the civil penalties levied against Organic Avenue in this case could exceed \$88,000.

However, as an alternative to a formal administrative proceeding, the NOP is offering the attached settlement agreement with reduced civil penalty of (b)(5) to resolve this matter. Please note that your cooperation and existing certification were considered in calculating the reduced settlement amount offered by the USDA. Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. Please sign the original and return it to the address noted below by \_\_\_\_\_\_, along with a (b)(5) certified check or money order made payable to the "Treasurer of the United States." Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave., SW Room 2646-S, STOP Code 0268 Washington, D.C. 20250-0268 Attn: Tammie Wilburn

If you have any questions regarding this notice, please contact Ms. Wilburn at <u>tammie.wilburn@ams.usda.gov</u> or 202-260-8638.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program

Enclosure - settlement agreement for signature



## NOTICE OF CIVIL PENALTY

Douglas Evans Chief Executive Officer Organic Avenue 43-47 9<sup>th</sup> Street Long Island City, New York 11101 dougevans@organicavenue.com

OCT 09 2012

Re: NOPC-053-12 Organic Avenue

Dear Mr. Evans:

The U.S. Department of Agriculture (USDA) National Organic Program (NOP) implements the Organic Foods Production Act of 1990 (OFPA) and its implementing regulations under 7 CFR Part 205. All agricultural products sold, labeled or represented as organic must be certified by a USDA-accredited certifying agent (ACA) and produced and handled in compliance with the USDA organic regulations.

As you know, in 2011 the NOP received a complaint alleging that Organic Avenue violated the NOP regulations by selling, labeling and representing its products as "100% organic" and "organic" without certification. Our investigation into the complaint found numerous claims at <u>www.organicavenue.com</u> to substantiate this allegation. We also found that your products were labeled and misrepresented as organic by use of the trade name "Organic Avenue."

As a result of our initial findings, on June 25, 2012, the NOP issued Organic Avenue a Notice to Cease and Desist (Notice) violating of OFPA and the NOP regulations. In response to the Notice, you agreed to update your website to comply with the regulations. You also advised that effective May 2012, Organic Avenue had achieved organic certification for handling from Oregon Tilth Certified Organic (OTCO). In later communication with OTCO, we were informed that OTCO issued Organic Avenue certification based on a full facility inspection only, and that no products or labels have yet been listed or approved for organic representation. Nonetheless, Organic Avenue continues to sell its products, labeled as "organic," without the labels having been approved by OTCO.

Finally, further investigation into the complaint found information dating back to at least the year 2004, a timeframe of 8 years, where Organic Avenue has misrepresented either itself or its agricultural products as organic, without certification, via product labeling and market information on the Internet, in violation of OFPA and the USDA organic regulations.



The aforementioned findings are in direct violation of the regulations. Paragraph 205.100(c) of the 7 CFR 205 states that any operation that knowingly sells or labels a product as organic, except in accordance with OFPA, shall be subject to a civil penalty of not more than \$11,000 per violation. Based on the evidence of this case, the NOP could pursue this matter by requesting a formal administrative proceeding and filing a complaint alleging the above referenced violations. If filed, the case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Given the continuing violations concerning product labeling and number of years (8) in violation of the USDA organic regulations, the civil penalties levied against Organic Avenue in this case could far exceed \$11,000.

As an alternative to a formal administrative proceeding and to resolve this matter, the NOP is offering the attached settlement agreement, which includes a reduced civil penalty of \$8,000 and an agreement by Organic Avenue to immediately comply with the USDA organic regulations. Please note that your cooperation and recent certification were considered in calculating the reduced settlement amount offered by the USDA. Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. Please sign the original and return it to the address noted below by **October 26, 2012**, along with a \$4,000 certified check or money order made payable to the "Treasurer of the United States." The remaining \$4,000 should be paid by **December 3, 2012**. Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave., SW Room 2646-S, STOP Code 0268 Washington, D.C. 20250-0268 Attn: Tammie Wilburn

If you have any questions regarding this notice, please contact Ms. Wilburn at tammie.wilburn@ams.usda.gov or 202-260-8638.

Sincerely,

Miles V. McEvoy

Deputy Administrator National Organic Program

Enclosure - settlement agreement for signature

cc: Connie Karr, OTCO (CCOF)



## NOTICE OF CIVIL PENALTY

Douglas Evans Chief Executive Officer Organic Avenue 43-47 9<sup>th</sup> Street Long Island City, New York 11101 dougevans@organicavenue.com

SEP 24 2012

Re: NOPC-053-12 Organic Avenue

Dear Mr. Evans:

The U.S. Department of Agriculture (USDA) National Organic Program (NOP) implements the Organic Foods Production Act of 1990 (OFPA) and its implementing regulations under 7 CFR Part 205. All agricultural products sold, labeled or represented as organic must be certified by a USDA-accredited certifying agent (ACA) and produced and handled in compliance with the USDA organic regulations.

As you know, in 2011 the NOP received a complaint alleging that Organic Avenue violated the NOP regulations by selling, labeling and representing its products as "100% organic" and "organic" without certification. Our investigation into the complaint found numerous claims at <u>www.organicavenue.com</u> to substantiate this allegation. We also found that your products were labeled and misrepresented as organic by use of the trade name "Organic Avenue."

As a result of our initial findings, on June 25, 2012, the NOP issued Organic Avenue a Notice to Cease and Desist (Notice) violating of OFPA and the NOP regulations. In response to the Notice, you agreed to update your website to comply with the regulations. You also advised that effective May 2012, Organic Avenue had achieved organic certification for handling from Oregon Tilth Certified Organic (OTCO). In later communication with OTCO, we were informed that OTCO issued Organic Avenue certification based on a full facility inspection only, and that no products or labels have yet been listed or approved for organic representation. Nonetheless, Organic Avenue continues to sell its products, labeled as "organic," without the labels having been approved by OTCO.

Finally, further investigation into the complaint found information dating back to at least the year 2004, a timeframe of 8 years, where Organic Avenue has misrepresented either itself or its agricultural products as organic, without certification, via product labeling and market information on the Internet, in violation of OFPA and the USDA organic regulations.

The aforementioned findings are in direct violation of the regulations. Paragraph 205.100(c) of the 7 CFR 205 states that any operation that knowingly sells or labels a product as organic, except in accordance with OFPA, shall be subject to a civil penalty of not more than \$11,000 per



*violation.* Based on the evidence of this case, the NOP could pursue this matter by requesting a formal administrative proceeding and filing a complaint alleging the above referenced violations. If filed, the case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Given the continuing violations concerning product labeling and number of years (8) in violation of the USDA organic regulations, the civil penalties levied against Organic Avenue in this case could far exceed \$11,000.

As an alternative to a formal administrative proceeding and to resolve this matter, the NOP is offering the attached settlement agreement, which includes a reduced civil penalty of and an agreement by Organic Avenue to immediately comply with the USDA organic regulations. Please note that your cooperation and recent certification were considered in calculating the reduced settlement amount offered by the USDA. Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. Please sign the original and return it to the address noted below by **October 15, 2012**, along with a <sup>(D)(6)</sup> certified check or money order made payable to the "Treasurer of the United States." Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave., SW Room 2646-S, STOP Code 0268 Washington, D.C. 20250-0268 Attn: Tammie Wilburn

If you have any questions regarding this notice, please contact Ms. Wilburn at tammie.wilburn@ams.usda.gov or 202-260-8638.

Sincerely,

Tucker Formum

Miles V. McEvoy Deputy Administrator National Organic Program

Enclosure - settlement agreement for signature

cc: Connie Karr, OTCO (CCOF)



JUN 25 2012

Denise Mari, Owner Organic Avenue/ The Space of LOVE 115 Suffolk Street New York, New York 10002

Re: NOPC-053-12 Organic Avenue

## NOTICE TO CEASE AND DESIST

Dear Ms. Mari:

The U.S. Department of Agriculture National Organic Program (NOP) enforces the Organic Foods Production Act (OFPA) of 1990, as amended, and its implementing regulations in 7 CFR 205. The NOP regulations at 7 CFR 205.100(a) require that except for operations exempt or excluded, all production and handling operations that sell, label or represent agricultural products as "100% organic, "organic" or "made with organic" ingredients be certified by a USDA-accredited certifying agent and comply with the NOP regulations. Our regulations can be found at www.ams.usda.gov/nop.

The NOP received a complaint alleging that Organic Avenue is in violation of the NOP regulations by selling, labeling and representing its products as "100% organic" and "organic" without certification. The complaint specifically references statements made on the Organic Avenue website claiming that all of Organic Avenue's products are organic. Our initial investigation into the complaint finds that Organic Avenue's product labels and marketing information violate the OFPA and the NOP regulations in numerous instances. The violations fall into two categories:

 At numerous locations on the Organic Avenue website (<u>www.organicavenue.com</u>) you claim that Organic Avenue products are organic. For example, on your "FAQ" page (<u>https://www.organicavenue.com/why\_love\_faq.php#are-all-products-organic</u>) the following text is presented:

Are your products all organic? Yes! Every ingredient is 100% organic always and local when possible. In addition to buying certified organic produce, we love supporting small farmers who use organic methods yet can't afford USDA certification. We also purchase wild, unsprayed produce, like our delicious Thai coconuts.

## NOPC-053-12 Organic Avenue Page 2

As stated above, similar violations occur elsewhere on your website, either as general statements or in descriptions of specific products. Organic Avenue products may not be sold, labeled or represented as "organic" because they are not produced and handled in accordance with the requirements of the OFPA and the NOP regulations.

2. The use of the trade name "Organic Avenue" on the principal display panel of the labeling of numerous of your products falsely implies that those products are produced and handled in compliance with the OFPA and the NOP regulations. The OFPA, under 7 USC 6505(a)(1)(B), requires that "no person may affix a label to, or provide other market information concerning, an agricultural product if such label or information implies, directly or indirectly, that such product is produced and handled using organic methods, except in accordance with this chapter." Organic Avenue may not use this trade name to imply that its products are produced and handled in accordance with the OFPA and the NOP regulations.

Be advised that Organic Avenue must immediately **CEASE AND DESIST** violation of the requirements in the OFPA and the NOP regulations. Failure to take action in this matter may result civil penalties of \$11,000 for each violation identified.

Within 10 business days of receipt of this letter, please notify the NOP in writing of your plan to come into compliance with the regulations. You may submit your written response to Tammie Wilburn, Compliance Specialist, at <u>Tammie.Wilburn@ams.usda.gov</u>. Ms. Wilburn can also be reached at (202) 720-3252.

Sincerely,

Ang hi lo

Matthew Michael Director, Compliance and Enforcement Division National Organic Program



## **Certification Acknowledgement**

This is to certify that

Organic Avenue 43-47 9th Street Long Island City, NY 11101 United States

is Certified Organic by Oregon Tilth under the US National Organic Program 7 CFR Part 205

Scope: NOP-Handling

Client Identification Number: OT-013013

Certified Organic Products: Per attached System Plan Summary

Certified by OTCO since: 05/23/2012

NOP effective date: 05/23/2012

Anniversary Date: 05/23/2013

Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked.

Certificate Issue Date: 05/31/2012

Certificate Number: Z-03025-2008

Authorized by:

Chris Schreiner, Executive Director

Certificate Number: Z-03025-2008

Doc - Certificate | Rev. 6/23/2011

Oregon Tilth, Inc. 260 SW Madison Ave., Suite 106 Corvallis, OR 97333, USA • PH: 1-503-378-0690 • FX: 1-541-753-4924 • www.tilth.org • organic@tilth.org



# **Organic System Plan Summary**

Organic Avenue 43-47 9th Street Long Island City, NY 11101 United States Client Identification Number: OT-013013

Certificate Issue Date: 05/31/2012

Certificate Number: Z-03025-2008

Certified by OTCO since: 5/23/2012

## **Certified Service (Organic)**

#### Service

#### Handling Other:

Services > Processing

#### Compliance

NOP-Handling

Certificate Number: Z-03025-2008 | Page 1 of 1

Doc - Certificate | Rev. 6/23/2011
June 27, 2012

Tammie Wilburn, Compliance Specialist National Organic Program 1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

Re: NOPC-053-12 Organic Avenue

Dear Ms. Wilburn,

Thank you for the notification and information regarding the U. S. Department of Agriculture National Organic Program (NOP). Our company, Organic Avenue, was founded in 2000, which is prior to the USDA NOP regulation. This clearly establishes the use of the word organic in our brand was to demonstrate to our customer base our commitment to holistic, ecologically balanced farming methods, and there was never intent to imply certification. However in May of this year, we did initiate the certification process and did receive organic certification as a handler from Oregon Tilth, Inc. (Attachment A)

I would like to specifically address your violations.

 Organic Avenue products being sold, labeled or represented as "organic" because they are not produced and handled in accordance with the requirements of OFPA and the NOP regulations.

We have removed the text you refer to in the specific violation on our website. As stated above, we achieved NOP certification as a handler with Oregon Tilth in May of this year. We are submitting formulations and labels for approval from Oregon Tilth at this time. All products with the Organic Avenue brand will be certified in the "organic" category (minimum 95% certified organic ingredients). Aaron Turner, from Oregon Tilth, is the reviewer on our file and can be reached at aaron@tilth.org or 541-740-9793.

 The use of the trade name "Organic Avenue" on the principal display panel of the labeling of products falsely implies that those products are produced and handled in compliance with OFPA and the NOP Regulations.

As stated above, we have achieved handler certification with Oregon Tilth and are submitting formulations and labels for approval.

We are working diligently with our certifier to get formulations and labels approved and then printed. Our plan is to have the process completed and implemented within 90 days.

If we can provide any further information please let me know. We are working with a consultant to foresee any future obstacles to assure our success in certification of these products.

(b)(6) Doug Evans C.E.O. Organic Avenue

From:	Jenna Preuss
To:	<u>Wilburn, Tammie - AMS</u>
Cc:	Doug Evans; Denise Mari
Subject:	Organic Avenue Response Letter
Date:	Thursday, July 05, 2012 12:53:21 PM
Attachments:	Organic Avenue Letter.pdf

Tammie,

Per Doug Evans' request, I am passing along a response letter from Organic Avenue. The original has been sent to your attention via Fedex.

Thanks, Jenna

\_\_\_

Jenna Preuss phone: 212-358-0500 ext. 145 email: jenna@organicavenue.com

Organic Avenue = LOVE\* Live. Organic. Vegan. Experience www.organicavenue.com



Organic Avenue LLC 116 Suffolk Street New York, NY 10002

October 1, 2012

Tammie Wilburn, Compliance Specialist National Organic Program 1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

Re: NOPC-053-12 Organic Avenue

Dear Ms. Wilburn,

We have received your Notice of Civil Penalty and Settlement Agreement. I am surprised and disturbed by the notice and the implications. I felt that we had a very productive call when we spoke the week of June 25<sup>th</sup>. The key point that you made was that there were companies that were intentionally falsely labeling and representing their products as USDA Organic and it was clear Organic Avenue was not operating under that premise.

Prior to any contact by you, we took the initiative to become USDA Certified Organic because we wanted to support the efforts and the standards of the governing agencies.

To your surprise, our plant had actually been certified already.

We have a few questions and clarifications regarding the notification.

First, your Notice acknowledges our agreement to update our website and our obtaining certification as a handler. However, our response also advised NOP that we were submitting labels and formulations to Oregon Tilth for approval. When you contacted them on September 11, 2012 we had submitted approximately 29 labels for approval, which had been ongoing since June. We never claimed to have products certified in our response but rather clearly stated we were in the process of label and formulation submission and approval. The certificate we submitted with our response only stated "processing" and did not list any products certified at that time.

Second, you noted that Organic Avenue has been doing business as Organic Avenue since at least 2004. However in our letter we were very clear that the company, Organic Avenue, was *founded and registered the domain in August, 1999 (Attachment A), which is prior to the USDA NOP regulation. This clearly establishes the use of the word organic in our brand was to demonstrate to our customer base our commitment to holistic, ecologically balanced* 

*farming methods, and there was never intent to imply certification.* (emphasis added re: text from original response)

Third, Oregon Tilth can verify that product formulations submitted were found to be primarily compliant in regards to ingredient sourcing, and the ingredients are not new ingredients. They are ingredients Organic Avenue has always been using prior to applying for certification in the Spring of 2012, so we only had to make minor changes to product formulations to achieve approval from Oregon Tilth. All of our ingredient sourcing is auditable for ingredients purchased to final product produced going back for many years. Further, our labels did not make any organic certification claim. On the principal display panel the only organic term used was in our trademarked company name. We did not sell or label any product as "organic". We did identify all the organic ingredients on the ingredient panel that were certified organic, and to restate, all of those purchase and production records are fully auditable to verify this.

In addition, in our response we clearly stated that *we are working diligently with our certifier to get formulations and labels approved and then printed. Our plan is to have the process completed and implemented within 90 days.* (emphasis added re: test from original response) Oregon Tilth will verify we have submitted all labels and formulations to have full certification within 90 days of the response.

Last, in your Notice to Cease and Desist you stated that within 10 business days we needed to notify the NOP in writing of our plan to come into compliance with the regulations. We had a phone call and submitted a plan that was based on 90 days, which is a reasonable time to submit formulations and labels for approval and have them printed. Oregon Tilth states certification will take an average of 90 days or more.

We are doing a great job spreading the organic message and promoting a healthy lifestyle in one of the most difficult markets to operate in.

Effective, Friday, September 28, 2012, all 29 of the Organic Avenue products submitted to Oregon Tilth, received their certification.

We painstakingly source USDA Certified Organic ingredients and pay a premium to do so.

The proposed penalty feels onerous and will have a tremendous financial impact on our company that has yet to have one year of profitability. We are a mission based business and are looking for support and encouragement

We would like to open a discussion regarding these issues before we determine the best next steps for our organization.

b)(6)

Doug Evans C.E.O. Organic Avenue Hi Tammie,

Thank you very much.

Happy Holidays to you too.

Love Doug

On Thu, Dec 20, 2012 at 3:57 PM, Wilburn, Tammie - AMS <<u>Tammie.Wilburn@ams.usda.gov</u>> wrote:

For your records Doug. Hard copies are being mailed. Happy Holidays!

Tammie

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

--LOVE\* Doug

# Hi Tammie,

The client and their consultant are asking us, OTCO, for copies of all correspondence between OTCO and the NOP about this issue. I just wanted to confirm with you that we are not obligated to provide this information to them. If we are, there is not a major issue in doing so, I just want to know what is required of us to do and what is confidential between the NOP and OTCO in this case.

Thanks, Connie Karr

CCOF and Oregon Tilth Announce Planned Merger

Our roots run deep. Now we are joining forces to grow the organic movement together. Visit <u>ccoftilthmerger.org</u> for more information.

This email and any files transmitted with it are privileged, confidential, subject to copyright and intended solely for the use of the individual or entity to whom they are addressed. Any unauthorized use, copying, review or disclosure is prohibited. Views expressed are those of the user and not necessarily those of Oregon Tilth, Inc. If you are not the intended recipient, you are hereby notified that any review, retransmission, conversion to hard copy, copying, circulation or other use of this message is strictly prohibited and may be illegal. Please notify the sender immediately if you have received this communication in error. Thank you for your assistance and cooperation.

# On Sep 24, 2012, at 12:59 PM, Wilburn, Tammie - AMS wrote:

Please see attached.

Best,

Tammie B. Wilburn Compliance and Enforcement National Organic Program U.S. Department of Agriculture 1400 Independence Avenue, SW Washington DC 20250 Tammie.Wilburn@ams.usda.gov

202-720-3252 – main office number 202-684-5465 - mobile 202-205-7808 - fax

Register for the NOP Organic Insider, the National Organic Program's email notification service, by visiting <u>http://bit.ly/NOPOrganicInsiderRegistration</u>.

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately. Dear Ms. Wilburn,

Thank you very much for your note.

I have prepared a detailed response.

Please let me know when your are available to discuss.

Sincerely,

Doug Evans C.E.O. Organic Avenue, LLC 917-859-7384

On Mon, Sep 24, 2012 at 3:58 PM, Wilburn, Tammie - AMS <<u>Tammie.Wilburn@ams.usda.gov</u>> wrote:

Mr. Evans,

The Department has concluded its review of the case filed against Organic Avenue. We are offering the attached notice of penalty and settlement in resolution of the violations to 7 CFR 205, the National Organic Program. Feel free to contact me should you have questions.

# Tammie B. Wilburn

Compliance and Enforcement

National Organic Program

U.S. Department of Agriculture

1400 Independence Avenue, SW

Washington DC 20250

Tammie.Wilburn@ams.usda.gov

202-720-3252 – main office number

<u>202-684-5465</u> - mobile

<u>202-205-7808</u> - fax

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LOVE\* Doug

\_\_\_

From:	Doug Evans
To:	Jenna Preuss
Cc:	Wilburn, Tammie - AMS; Denise Mari; Kristy Korb
Subject:	Re: Organic Avenue Response Letter
Date:	Thursday, July 05, 2012 1:01:30 PM

Hi Tammy,

Thank you for your support and counsel.

Please let us know what we need to do to be fully compliant.

Sincerely,

Doug

On Jul 5, 2012, at 12:53, Jenna Preuss <jenna@organicavenue.com> wrote:

> Tammie,

>

> Per Doug Evans' request, I am passing along a response letter from Organic

> Avenue. The original has been sent to your attention via Fedex.

>

> Thanks,

> Jenna

>

> ---

> Jenna Preuss

> \*phone: 212-358-0500 ext. 145\*

> \*email: jenna@organicavenue.com\*

>

> Organic Avenue = LOVE\* Live. Organic. Vegan. Experience

> www.organicavenue.com <<u>http://www.organicavenue.com</u>>

> <Organic Avenue Letter.pdf>

From:	Connie Karr
To:	<u>Wilburn, Tammie - AMS</u>
Cc:	Aaron Turner
Subject:	Re: Organic Avenue
Date:	Tuesday, September 11, 2012 10:33:20 PM
Attachments:	7 oz proofs fisrt Part.pdf

### Hi Tammie,

Attached are recent label submissions that have not yet been approved. Aaron reported to me that they had also submitted products at the end of July all of which were denied and returned to them with various issues and inconsistencies between labels and formulations. These attached labels were submitted very recently for approval but have not been fully reviewed yet.

Thanks, Connie Karr

CCOF and Oregon Tilth Announce Planned Merger

Our roots run deep. Now we are joining forces to grow the organic movement together. Visit <u>ccoftilthmerger.org</u> for more information.

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# On Sep 11, 2012, at 1:58 PM, Wilburn, Tammie - AMS wrote:

Connie,

Can you please send me a complete list of Organic Avenue labels submitted for approval. Have any been approved yet? Thanks, Tammie

From: Connie Karr [mailto:connie@tilth.org] Sent: Tuesday, July 10, 2012 1:42 PM To: Wilburn, Tammie - AMS Cc: Aaron Turner Subject: Re: Organic Avenue Importance: High

Dear Tammie,

Hope you are doing well. Aaron forwarded your email to me to respond to since I deal with most issue related to compliance and enforcement in the OTCO program. OTCO does indeed certify Organic Ave and they were first certified by us on 5/23/12 after a full facility inspection on 5/1/12. The certificate is attached. However, please be aware that there are no products yet listed on the certification that have been approved by OTCO. They do have several pending items ready to submit for review that have not yet been approved. They were

clearly reminded of the fact that no products were approved in their certification decision letter that was sent along with the certification.

Please let me know if you have any additional questions or if I can assist you in any way with this OTCO client.

# Thanks, Connie Karr

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Begin forwarded message:

From: "Wilburn, Tammie - AMS" <<u>Tammie.Wilburn@ams.usda.gov</u>> Date: July 10, 2012 8:40:58 AM PDT To: "<u>aaron@tilth.org</u>" <<u>aaron@tilth.org</u>> Subject: Organic Avenue

Hi Aaron,

I am following up on a complaint filed regarding Organic Avenue. In response to the complaint, Organic Avenue responded that they have achieved organic certification from OTCO. Can you please provide an update on their certification and a copy of the certificate if it is ready.

Many thanks!

Tammie B. Wilburn Compliance and Enforcement National Organic Program U.S. Department of Agriculture 1400 Independence Avenue, SW Washington DC 20250 Tammie.Wilburn@ams.usda.gov

202-720-3252 – main office number 202-260-8638 - mobile 202-205-7808 - fax

Register for the NOP Organic Insider, the National Organic Program's email notification service, by

visiting <u>http://bit.ly/NOPOrganicInsiderRegistration</u>.

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From:	Connie Karr
To:	<u>Wilburn, Tammie - AMS</u>
Cc:	Aaron Turner
Subject:	Re: Organic Avenue
Date:	Tuesday, July 10, 2012 1:41:58 PM
Attachments:	OTCO Certificate.pdf
Importance:	High

Dear Tammie,

Hope you are doing well. Aaron forwarded your email to me to respond to since I deal with most issue related to compliance and enforcement in the OTCO program. OTCO does indeed certify Organic Ave and they were first certified by us on 5/23/12 after a full facility inspection on 5/1/12. The certificate is attached. However, please be aware that there are no products yet listed on the certification that have been approved by OTCO. They do have several pending items ready to submit for review that have not yet been approved. They were clearly reminded of the fact that no products were approved in their certification decision letter that was sent along with the certification.

Please let me know if you have any additional questions or if I can assist you in any way with this OTCO client.

# Thanks, Connie Karr

This email and any files transmitted with it are privileged, confidential, subject to copyright and intended solely for the use of the individual or entity to whom they are addressed. Any unauthorized use, copying, review or disclosure is prohibited. Views expressed are those of the user and not necessarily those of Oregon Tilth, Inc. If you are not the intended recipient, you are hereby notified that any review, retransmission, conversion to hard copy, copying, circulation or other use of this message is strictly prohibited and may be illegal. Please notify the sender immediately if you have received this communication in error. Thank you for your assistance and cooperation.

Begin forwarded message:

From: "Wilburn, Tammie - AMS" <<u>Tammie.Wilburn@ams.usda.gov</u>> Date: July 10, 2012 8:40:58 AM PDT To: "<u>aaron@tilth.org</u>" <<u>aaron@tilth.org</u>> Subject: Organic Avenue

Hi Aaron,

I am following up on a complaint filed regarding Organic Avenue. In response to the complaint, Organic Avenue responded that they have achieved organic certification from OTCO. Can you please provide an update on their certification and a copy of the certificate if it is ready.

Many thanks!

# Tammie B. Wilburn

Compliance and Enforcement National Organic Program U.S. Department of Agriculture 1400 Independence Avenue, SW Washington DC 20250 Tammie.Wilburn@ams.usda.gov

202-720-3252 – main office number 202-260-8638 - mobile 202-205-7808 - fax

Register for the NOP Organic Insider, the National Organic Program's email notification service, by visiting <u>http://bit.ly/NOPOrganicInsiderRegistration</u>.

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately. Mr. Evans

This email confirms receipt of (b)(4) check (b)(4) from Organic Avenue LLC in the amount of \$4,000. This payment is one of two toward the \$8,000 penalty agreed to under settlement between Organic Avenue and the USDA National Organic Program. Receipt of payment two, due December 3, 2012, will close our files on this matter.

Best,

# Tammie B. Wilburn

Compliance and Enforcement National Organic Program U.S. Department of Agriculture 1400 Independence Avenue, SW Washington DC 20250 Tammie.Wilburn@ams.usda.gov

202-720-3252 – main office number 202-684-5465 - mobile 202-205-7808 - fax

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# SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and Organic Avenue, Long Island City, New York, and any person responsibly connected with Organic Avenue.

USDA, AMS and Organic Avenue have decided to compromise and settle the issues among them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and regulations promulgated thereunder (7 C.F.R. §§ 205 et seq.).

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to file a formal administrative complaint charging Organic Avenue with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. Organic Avenue agrees to the following:
  - A. Organic Avenue has been given the opportunity for a hearing and waives such hearing and further procedure for the purpose of settling this proceeding and for such purposes only.
  - B. Organic Avenue agrees that failure to comply with the settlement agreement shall automatically void number 2 above, and that USDA, AMS may thereafter institute a formal administrative proceeding against Organic Avenue, and pursue any and all remedies available under the OFPA and the regulations.
  - C. Organic Avenue agrees to immediately comply with the USDA organic regulations.
  - D. Organic Avenue agrees to pay a reduced penalty of \$<sup>(b)(5)</sup> in full settlement of this matter.

This agreement will become effective upon receipt of payment.

Douglas Evans Chief Executive Officer Organic Avenue Miles McEvoy Deputy Administrator National Organic Program, AMS, USDA

Date: \_\_\_\_\_

Date: \_\_\_\_\_



1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0268

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  - C. Organic Avenue agrees to immediately comply with the USDA organic regulations.
  - D. Organic Avenue agrees to pay a reduced penalty of <sup>(b)(6)</sup> 8,000, in two \$4,000 installments, in full settlement of this matter. The installments are due on
     D. October 26, 2012, and December 3, 2012.

This agreement will become effective upon receipt of final payment.

Douglas Evans Chief Executive Officer Organic Avenue Miles McEvoy Deputy Administrator National Organic Program, AMS, USDA

Date: \_\_\_\_\_

Date: \_\_\_\_\_

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Date:

Date:



1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0268

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  - C. Organic Avenue agrees to immediately comply with the USDA organic regulations.
  - D. Organic Avenue agrees to pay a reduced penalty of <sup>(0)(3)</sup> in full settlement of this matter.

This agreement will become effective upon receipt of payment.

Douglas Evans Chief Executive Officer Organic Avenue Miles McEvoy Deputy Administrator National Organic Program, AMS, USDA

Date:

Date:

SDA Agricultural Marketing Service 1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0268

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Inthe O

Miles McEvoy Deputy Administrator National Organic Program, AMS, USDA

Date: 12/20/2012

Douglas Evans Chief Executive Officer Organic Avenue

Date: 10 15 12-



# **Global Organic Alliance, Inc.**

PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530 Phone: 937 593 1232 Fax 937 593 9507 Email: goaor@centurylink.net Website: www.goa-online.org

April 12, 2013

Joseph Lloyd NOP Appeals Team 1400 Independence Ave, SW Room 2095-S Stop 0203 Washington, D C 20250

Received By **AMS** Compliance 4.15.2013 Initials Date

Phone: 202-720-6766

Re: Appeal Response, APL-027-13

Dear Joseph:

Enclosed please find copies of all documents pertaining to the Appeal from Rosewood Products dba GreenHope, as requested.

Should you require further information, please contact the undersigned.

GOA did not receive a copy of the Appeal sent to the NOP Compliance Dept. by Mr. Phillip Ye of GreenHope, we would appreciate very much if you could forward a copy for our files.

Sincerely,

Betty Kamanen President/CEO

c: master file Phil Ye, GreenHope





April 8, 2013

1400 Independence Ave. SW Room 2095 - South, STOP 0203 Washington, D.C. 20250

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 USA

# Re: Appeal Acknowledgement, APL-027-13

Dear Phil Ye,

This is to acknowledge your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation of National Organic Program (NOP), sent by Global Organic Alliance (GOA). This appeal will be reviewed, heard, and decided by persons not involved with the decision being appealed. Within 30 days of receipt of this letter, please provide the NOP Appeals Team a copy of the Notice of Noncompliance and Proposed Revocation as well as any additional information you believe would support your appeal and demonstrates your compliance with the NOP regulations.

Control Number **APL-027-13** has been assigned to this appeal. Please use this control number on all correspondence regarding this appeal. All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. Sending any correspondence to an incorrect address or by a delivery service that does not adequately provide dated return receipts will jeopardize the procedural status of the appeal and it may be rejected. It is acceptable to submit information by fax or email as well.

During the appeal process your organic certification status remains valid. As such, any products marketed as organic must meet all regulatory requirements of the NOP. Please note that you must file additional appeals if your accredited certifying agent issues any additional proposed suspensions or proposed revocations.

Sincerely,

Joseph Lloyd NOP Appeals Team 1400 Independence Ave., SW Room 2095-S, Stop 0203 Washington, D.C. 20250 Phone: (202) 720-6766 Fax: (202) 205-5772 <u>NOPAppeals@ams.usda.gov</u>

Cc: Betty Kananen, GOA Miles McEvoy, NOP



April 8, 2013

1400 Independence Ave. SW Room 2095 - South, STOP 0203 Washington, D.C. 20250

Global Organic Alliance (GOA) Betty Kananen PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530

# Re: Appeal Acknowledgement, APL-027-13

Dear Global Organic Alliance (GOA)

This is to acknowledge that Rosewood Products appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation of National Organic Program (NOP), was received by the Administrator on April 8, 2013. This appeal will be reviewed, heard, and decided by persons not involved with the decision being appealed. Within 30 days from receipt of this letter, please provide the NOP Appeals Team with a copy of the documents supporting the Notice of Noncompliance and Proposed Revocation.

Control Number **APL-027-13** has been assigned to this appeal. Please use this control number on all correspondence regarding this appeal. All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. Sending any correspondence to an incorrect address or by a delivery service that does not adequately provide dated return receipts will jeopardize the procedural status of the appeal and it may be rejected. It is acceptable to submit information by fax or email as well.

During the appeal process Rosewood Products's organic certification status remains valid. As such, any products marketed as organic must meet all regulatory requirements of the NOP. Please note that this means that Global Organic Alliance (GOA) must continue to monitor Rosewood Products under the NOP regulations. Please note that Global Organic Alliance (GOA) may issue additional noncompliance notifications; Rosewood Products may file additional appeals if Global Organic Alliance (GOA) issues additional proposed suspensions or proposed revocations.

Sincerely,

Joseph Lloyd NOP Appeals Team 1400 Independence Ave., SW Room 2095-S, Stop 0203 Washington, D.C. 20250 Phone: (202) 720-6766 Fax: (202) 205-5772 <u>NOPAppeals@ams.usda.gov</u>



# **NOP APPEALS DECISION**

**Clearance Document** 

Appellant:Rosewood ProductsAppeal #:APL-027-13

# \*\*\* REVISED – SETTLEMENT AGREEMENT \*\*\*

# **NOP Associate Deputy Administrator**

\_\_\_\_\_ Approved

\_\_\_\_\_ (signature & date)

Jennifer Tucker

# **NOP Deputy Administrator**

\_\_\_\_\_ Approved

\_\_\_\_\_ Substantive disagreement – details attached

\_\_\_\_\_ Minor editorial changes

\_\_\_\_\_ (signature & date)

Miles McEvoy



# Global Organic Alliance, Inc.

PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530 Phone: 937 593 1232 Fax 937 593 9507 Email: goaorg@centurylink.net Website: www.goa-online.org

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Sincerely,

(0

Betty Kananen President/CEO

c: master file Phil Ye, GreenHope

letterhead

# **Betty Kananen**

From: Sent: To: Subject: Rakola, Betsy - AMS <Betsy.Rakola@ams.usda.gov> Thursday, February 07, 2013 3:26 PM Betty Kananen RE: <No Subject>

Received By A Compliance 4.(6.2013 Initials Date

Thanks, Betty. Your accreditation certificate is in the mail.

Regarding the operation with the FDA violations, GOA has complied with its responsibility to report the violation to the NOP. I will forward this to compliance. If you are seeking adverse actions against the operation, those would need to be cited to a violation of the USDA organic regulations. It sounds like you would be looking at the §§205.207-272 sections in this case for a relevant citation.

Best,

Betsy Rakola

Agricultural Marketing Specialist, USDA-AMS National Organic Program Tel 202-690-1312 Fax 202-205-7808 www.ams.usda.gov/NOP

From: Betty Kananen [mailto:goaorg@centurylink.net] Sent: Thursday, February 07, 2013 10:16 AM To: Rakola, Betsy - AMS Subject: <No Subject>

Thank you Betsy,

I have attached the signed "Terms of Accreditation. Processor Magazine Article. and NOP Policy 11-6.

Also-I need your guidance on a situation.

Greenhope is a facility we have certified in the past and is up for renewal. They were inspected January 7, 2013 for GOA.

Sequence of events.

File to inspector with instructions to inspect while processing certified product. Inspector "heard" they were under investigation for food safety problems and went in with this in mind. He found them to be following all requirements during his visit. No mention of the court order or any other issues regarding their problem was made to the inspector. The inspector found this article in the Processor magazine and forwarded to me. Per the attached Policy 11-6, we turn everything over to the NOP.

Please guide me, where do we go from here? What will be required of GOA to send to whom? This facility will be on "hold" until we hear from you.

Frankly, I do not want neither GOA or "organic" anywhere near these people, but will follow protocol.

Thanks so much for your time and guidance.

### Global Organic Alliance

### Green Hope dba Rosewood Products

Response to B. Rahala recordent 15 February 2013

1. What is "At issue" or your "Question"?

How should GOA proceed? Issue a Notice of Noncompliance? Issue a combined Notice of Noncompliance and Proposed Revocation? Can a noncompliance be issued based on a policy memorandum? Will the compliance department direct GOA on how to proceed so that we do not "screw up" and have it thrown out?

- 2. Relevant Standard(s):
  - §205.400 General Requirements for Certification

     (f) Immediately notify the certifying agent concerning any:
     (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.
  - §205.662 Noncompliance procedure for certified operations
     (d) Willful violations. Notwithstanding paragraph (a) of this section, if a certifying agent...has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent...shall send the certified operation a notification of proposed...revocation of certification of the entire operation.....

(g) Violations of Act. In addition to suspension or revocation, any certified operation that:(2) Makes a false statement under the Act to....a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

- PM 11-6 Reporting Health and Safety Violations. First paragraph, third sentence: "Further, organic certification shall not be granted or continued when current health or safety inspections have not been granted or renewed for the facility.
- 3. Background

Green Hope dba Rosewood has entered a consent decree of permanent injunction with the FDA for food safety violations on January 28, 2013. On January 7, 2013 an on-site inspection took place while product was being made. The inspector did not observe any violations at this time. According to the new release by the Department of Justice, the Food and Drug Administration (FDA) has found violations involving sanitary conditions dating back to 2009. Apparently this has been going on since Green Hope dba Rosewood was first inspected and certified under Phil Ye in 2009.

### 4. Proposed Solutions(s)

Revocation of organic certification for providing false information to GOA and the inspector for GOA and endangering of the organic tofu. Mr. Ye is a difficult person to work with and comes across as being above the regulations. He has gone so far as calling the CEO a "Nazi". From the initial application in 2009, GOA was not notified or informed at any time about the FDA proceedings and pending sanctions, including during the on-site inspection on January 7, 2013, three-weeks to the day they entered into the consent decree with the FDA. Mr. Ye had to know this was going to happen at the time of the inspection.

### 5. Attachment(s)

- FDA Warning Letter 2011-DET-08, May 6 2011
- Department of Justice News Release, January 28, 2013
- Processing Magazine Article, Soy processor Green Hope to halt operations over food safety breaches, February 6, 2013.
- Policy Memorandum 11-6, Reporting Health & Safety Violations

### 6. Urgency

GOA is ready to proceed with the decision-making process for this file.



# Soy processor Green Hope to halt operations over food safety breaches

February 6, 2013

U.S. organic soy processing firm Green Hope LLC has agreed to a consent decree of permanent injunction after several inspections by regulators found food safety violations at its plant.

The consent decree was issued to Green Hope, which trades as Rosewood Products, and owner Phi G. Ye, of Ann Arbor, Michigan, by Judge David M. Lawson of the U.S. District Court for the Eastern District of Michigan, Southern Division. The court order was signed on Jan. 28, 2013, the <u>U.S. Food</u> and Drug Administration (FDA) said.

Multiple inspections by the FDA found that the company was persistently violating sanitary requirements at its facility, leading to potential contamination of its food products. Green Hope manufactures and distributes ready-to-eat (RTE) organic tofu, soy milk and other products to companies in Michigan and Minnesota.

# **RELATED: Food-safety Compliant Globe Valves**

Specifically, the FDA inspections found that the firm did not store the food properly, did not address employee cleanliness issues, allowed waste water to come in contact with tofu during processing and failed to clean all food-contact surfaces and equipment. The violations involving insanitary conditions included company employees touching tofu with bare, uncovered arms. One worker was found to use his mouth to siphon liquid through a plastic hose from a kettle with ready-to-eat tofu in it. The company was sent a <u>warning letter</u> on May 6, 2011 informing it of the serious violations found by the FDA inspectors. No illnesses associated with the use of Green Hope's products have been reported to date.

The firm must now halt operations until the FDA approves the measures taken to bring its operations into full conformity with the food safety regulations of the FDA and the Federal Food, Drug and Cosmetic Act. Green Hope must hire an independent expert to prepare a written sanitation control program and staff training program. Another step for regaining full compliance with the food safety requirements includes assigning a company employee to conduct and maintain the sanitation control program. Green Hope is further required to make structural repairs to its facility to protect against contamination of input materials, in-process and finished foods, packaging materials and containers.

The FDA may make additional inspections at the facility at any time to ensure the steps are being implemented. The company is also required to cover all costs related to the inspections, supervision, examinations, analyses and reviews carried out by the FDA in relation to this consent decree.

Home Inspections, Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters Inspections, Compliance, Enforcement, and Criminal Investigations Green Hope LLC dba Rosewood

Department of Health and Human Services

Public Health Service Food and Drug Administration Detroit District 300 River Place Suite 5900 Detroit, MI 48207 Telephone: 313-393-8100 FAX: 313-393-8139

WARNING LETTER 2011-DET-08

May 6, 2011

VIA UPS

Mr. Phil G. Ye, Owner Green Hope, LLC dba Rosewood 738 Airport Bivd Suite 6 Ann Arbor, MI 48108-1674

Dear Mr. Ye:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your food processing facility, located at 738 Airport Bivd Suite 6, Ann Arbor, MI on February 28 through March 16, 2011. The inspection revealed serious violations of FDA's Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMP) regulation, Title 21, Code of Federal Regulations Part 110 (21 CFR Part 110). These conditions cause the food products produced in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(a)(4)] in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health. You may find the Act and the CGMP regulation through links on FDA's home page at www.fda.gov<sup>1</sup>.

#### The following violations were observed during the inspection:

1. You failed to ensure that all persons working in direct contact with food conform to hygienic practices while on duty, by taking necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with micro-organisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin, as required by 21 CFR 110.10(b)(9). Specifically:

- On 3/1/2011, during the processing of ready-to-eat tofu, an employee used his mouth to siphon liquid through a plastic hose from a kettle containing
  approximately (b)(4) gallons of ready to eat tofu after the coagulation process had occurred. The inside surface of that same hose contained a heavy
  accumulation of adhering white colored residue. The likelihood of microbial cross contamination from possible backflow from the employee's mouth to
  finished product tofu was further increased by a lack of designation as to which end of the hose was to come in contact with the employee's mouth and which
  end was to be submerged into the product.
- On at least three occasions, two employees used their mouths and plastic hoses to siphon water from a 35-gallon container, which was being used as a weight on top of tofu racks during the pressing operation. Water from that same container was overflowing and leaking down onto the uncovered racks of ready to-eat tofu below.
- On 2/28/2011, three employees lowered racks of unwrapped ready-to-eat tofu down into an ice water bath in a tank, with their bare, uncovered arms exposed. The employees' bare uncovered arms then came in direct contact with the water being used to cool un-wrapped tofu.

2. You failed to conduct food manufacturing under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or the contamination of food, as required by 21 CFR 110.80(b)(2). Specifically:

- An employee was observed using a white plastic scoop to remove foam from the top of post steamed soy milk, then lowering the scoop to within 2 feet of the
  production room floor and then rinsing it with pressurized water which forced water spray droplets bounding from the floor to come into direct contact with
  the scoop. That same scoop was then immediately re-used to remove more foam from the kettle with no cleaning or sanitizing between uses. After the
  employee was instructed by your firm's management to cease this action, another employee was observed rinsing a strainer in the same manner and then
  using it in direct contact with un-pressed ready-to-eat tofu curds.
- An employee used a pressurized water hose to spray the outside of a kettle containing approximately (b)(4) gallons of unfiltered soy milk (pre-steaming) and water spray droplets were observed impacting the workroom floor and then aerosolizing near the opening of the same kettle.
- An employee used a pressurized water hose to spray a strainer used to scoop raw soybeans into a hopper approximately two feet above the workroom floor and about five feet from uncovered filtered say milk. Soybean waste and excess foam residue was observed on the work room floor and the aerosolized water spray droplets impacting the floor were observed in direct contact with the strainer, which was later used to scoop raw soy beans with no cleaning or san(tizing before use.
- Water spray from a pressurized water hose being used by an employee was impacting the work room floor and then aerosolizing back onto the food contact surface of a previously cleaned pressing table used for manufacturing ready-to eat tofu. According to firm management, this same table was not cleaned and sanitized prior to the next tofu production.

3. You failed to ensure that all persons working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against contamination of food by washing their hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated, as required by 21 CFR 110.10(b)(3). Specifically:

- On 2/28/2011, 3/1/2011, and 3/2/2011 an employee touched heavily solied mechanical power switches, which were covered with thick black colored
  residue, and then immediately placed his hands into cooling steamed soymilk to remove the film formed on top, known as tofu skin. The employee did not
  wash and sanitize his hands prior to touching the soy milk and tofu skins. These switches are routinely used during production to control the product
  transport pump and a power strip.
- On 2/28/2011, 3/1/2011, and 3/2/2011, employees handled a pressurized water hose spray nozzle/handle which was heavily solied with black colored residue and rust and then immediately handled ready-to-eat tofu with no hand washing and sanitizing between jobs.
- On 3/1/2011, an employee used a floor squeegee that was touching the North wall to press down or compact soybean waste into a garbage can and then his
  hands came into direct contact with ready-to-eat tofu curds while he was wrapping them with towels during the pressing process. The North wall contained



# **Betty Kananen**

From:	Betty Kananen <goaorg@centurylink.net></goaorg@centurylink.net>
Sent:	Thursday, February 07, 2013 10:16 AM
То:	'Rakola, Betsy - AMS (Betsy.Rakola@ams.usda.gov)'
Attachments:	SKMBT_C45213020710520

Thank you Betsy,

I have attached the signed "Terms-of-Accreditation." Processor Magazine Article. and NOP Policy 11-6.

Also-I need your guidance on a situation.

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Thanks so much for your time and guidance.

Betty



1400 Independence Ave. SW Room 2648 - South, STOP 0268 Washington, D.C. 20250

July 18, 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108

# **RE:** Proposed Settlement Agreement for APL-027-13

Dear Phil Ye:

The National Organic Program (NOP) Appeals Team has evaluated your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation issued by Global Organic Alliance, Inc. regarding Rosewood Products' NOP certification.

Global Organic Alliance had proposed a revocation of your NOP certification, which would make you ineligible for NOP organic certification for five years. The NOP would like to offer you a settlement agreement that would reduce this penalty to a six month suspension.

A copy of this settlement is enclosed for your consideration. If you agree to the terms, please sign the Agreement, and return the original to the address below within 10 days of receipt of this letter.

You are entitled to consult with an attorney. You may accept or reject this proposed settlement. If you choose to sign and date the settlement agreement, please retain a copy for your files.

If you have any questions, please contact me at <u>Jennifer.Tucker@ams.usda.gov</u> or by phone at 202-260-8077.

Sincerely,

Jennifer Tucker, Ph.D. Associate Deputy Administrator National Organic Program 1400 Independence Avenue, S.W. Room 2648-S, STOP 0268 Washington, D.C. 20250

cc: Betty Kananen – Global Organic Alliance, Inc.

Enclosure: Proposed Settlement Agreement


July 26, 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108

#### RE: Follow-up to Request Related to Proposed Settlement Agreement for APL-027-13

Dear Mr. Ye:

Thank you for your call earlier this week concerning the National Organic Program's (NOP) Proposed Settlement to resolve your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation issued by Global Organic Alliance, Inc. regarding Rosewood Products' NOP certification.

During our call, you asked that the NOP reconsider the settlement agreement to remove the six month suspension and potentially replace it with a civil penalty. After reviewing your case again, we have determined that we cannot grant this request. Rosewood used a prohibited substance for an extended period of time in its processing operations; this is a significant violation of the USDA organic regulations. As such, the proposed settlement we offered you on July 18, 2013 stands.

We understand that you may need more time to reconsider the settlement in light of this decision; as such, we are giving you another <u>10 days</u> from receipt of this letter to consider your response. As noted previously, you are entitled to consult with an attorney. You may accept or reject this proposed settlement. If you choose to sign and date the settlement agreement, please retain a copy for your files.

If you have any questions, please contact me at <u>Jennifer.Tucker@ams.usda.gov</u> or by phone at 202-260-8077.

Sincerely,

Jennifer Tucker, Ph.D. Associate Deputy Administrator National Organic Program 1400 Independence Avenue, S.W. Room 2648-S, STOP 0268 Washington, D.C. 20250



October 29, 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 Transmittal by email: philye@rosewoodproducts.com

#### **RE:** Revised Proposed Settlement Agreement for APL-027-13

Dear Mr. Ye:

The USDA Agricultural Marketing Service and the National Organic Program (NOP) have continued to evaluate your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation issued by Global Organic Alliance, Inc. regarding Rosewood Products' NOP certification. As a result of this evaluation, we have decided to reconsider the parameters of a proposed settlement agreement with you.

The determination that Rosewood Products violated the USDA organic regulations stands. Rosewood violated two sections of the USDA organic regulations with the use of the defoamer for an extended period of time in its processing operations. Section 205.201(a)(2) requires that an organic system plan include "a list of each substance to be used as a production or handling input." Given that the defoamer was not included in its handling plan, Rosewood violated this section. Rosewood also violated 7 CFR 205.105 (Allowed and Prohibited Substances). During its January 7, 2013 inspection, GOA observed that Rosewood used a prohibited substance in its operation. GOA noted, "Chemco Defoamer DF 410, a defoaming agent that is sprayed into the soymilk and filter tank, is prohibited. This product contains a nonagricultural ingredient (hydrophobic silica) that is not listed in 7 CFR 205.605; therefore, it is prohibited."

Furthermore, a review of the FDA findings suggests that Rosewood's associated violations, including incorrect cleaning practices, could also impact the operation's compliance with the USDA organic regulations, specifically 7 CFR 205.272(a) (Commingling and contact with prohibited substance prevention practice standard), given that Rosewood is a mixed (conventional and organic) operation. Rosewood should have informed its certifier of the FDA's findings.

Rosewood noted in its appeal and in its additional communication that it inherited its operations from a previous owner, and further claimed that GOA is responsible for not having detected the prohibited substance problem. However, it is Rosewood's responsibility, not GOA's, to report all inputs used in its organic operation and to maintain compliance, regardless of the operational practices in place before the current owner inherited the operation.



Based on these non-compliances, GOA had proposed a revocation of Rosewood's NOP certification, which would make it ineligible for NOP organic certification for five years. Failure to comply with the USDA organic regulations can result in suspension, revocation, *and/or* penalties of up to \$11,000 *per violation*.

Rather than proceeding with an AMS Administrator's Decision, which could lead to suspension or revocation, the NOP would like to offer you a revised settlement agreement that would allow Rosewood to keep its organic certification, and clear the violations with a civil penalty instead.

A copy of this settlement is enclosed for your consideration. **If you agree to the terms of this revised settlement, please sign the Agreement, and return the original to the address in the signature below within 10 days of receipt of this letter.** Your signed agreement must include either: (1) a check or money order for \$11,000 made payable to the Treasurer of the United States; or (2) a proposed payment schedule, if you are unable to make the payment in full at this time.

If you have any questions, please contact me at <u>Jennifer.Tucker@ams.usda.gov</u> or by phone at 202-260-8077.

Sincerely,

21 Tucker

Jennifer Tucker, Ph.D. Associate Deputy Administrator National Organic Program 1400 Independence Avenue, S.W. Room 2648-S, STOP 0268 Washington, D.C. 20250

cc: Betty Kananen – Global Organic Alliance, Inc. (<u>goaorg@centurylink.net</u>) Gary Peters – Howard and Howard (<u>gpeters@HowardandHoward.com</u>)

Enclosure: Proposed Settlement Agreement



# National Organic Program (NOP) Appeal APL-027-13

## (For Administrator Signature)

Appellant:

Green Hope LLC dba Rosewood Products Phil Ye 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108

**Certifying Agent:** 

Global Organic Alliance, Inc. Betty Kananen PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530

## PLEASE RETURN TO NOP: (202) 720-3252

Reviewed by:	Initials/Date
Deputy Administrator, NOP	
AMS Associate Administrator	

### UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE BEFORE THE ADMINISTRATOR

In re: Rosewood Products Phil Ye	) ) )	Administrator's Decision APL-027-13

(b)(5)

(b)(5)

(b)(5)



September XX, 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 Transmittal by certified email: <u>philye@rosewoodproducts.com</u>

#### RE: APL-027-13 - National Organic Program Appeal<sup>(D)(5)</sup>

Dear Mr. Ye:

The evaluation of your appeal regarding the March 12, 2013 Notice of Noncompliance and Proposed Revocation issued by Global Organic Alliance, Inc. (GOA has concluded. <sup>(b)(5)</sup>

(b)(5)

b)(5)

If you have any questions,

please contact me at (202) 260-8077 or via email at Jennifer.Tucker@ams.usda.gov.

Sincerely,

Jennifer Tucker Associate Deputy Administrator USDA National Organic Program

Cc: Betty Kananen, GOA (goaorg@centurylink.net) Peters, Gary A., Howard and Howard (gpeters@HowardandHoward.com)

Enclosures: Administrator's Decision; (b)(5)



#### Global Organic Alliance, Inc. PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530 Phone: 937 593 1232 Fax: 937 593 9507 Email: goaorg@centurvlink.net Website: www.goa-online.org

#### SENT VIA: CERTIFIED MAIL RETURN RECEIPT and REGULAR MAIL

12 March 2012

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 USA

#### Subject: Notice of Noncompliance and Proposed Revocation

Dear Phil:

This letter is an official Notice of Noncompliance and Proposed Revocation pursuant to section §205.662 of the USDA National Organic Program Regulations. The proposed revocation is based on noncompliances observed during the on-site inspection of your handling operation in Ann Arbor, MI on January 7, 2013 and response to our request for additional information.

The reason for the proposed revocation is that you failed to comply with the following two sections of the National Organic Program Regulations:

- 1. § 205.400 General requirements for certification. A person seeking to receive or maintain organic certification under the regulations in the part must:
  - (f) Immediately notify the certifying agent concerning any:
    - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.
    - Global Organic Alliance was not notified of the Food and Drug Administration (FDA) proceedings
      regarding Green Hope that have taken place since 2009 and that Green Hope was entering into a consent
      decree of permanent injunction for food safety violations on January 28, 2013 with the FDA. Three-weeks
      to the day of the annual on-site inspection on January 7, 2013 for continued organic certification.

Failing to notify Global Organic Alliance of the packaging and private labeling arrangement with (b)(4) and submitting the Rosewood 'organic' private label for review and approval.

- Failing to notify Global Organic Alliance of the addition of a defoamer as a processing aid in making the tofu products.
- 2. § 205.105: Allowed and prohibited substances, methods, and ingredients in organic production and handling. To be sold, labeled, or represented as "100 percent organic", "organic", or 'made with organic (specified ingredients or food group(s))," the product must be produced and handled with the use of: (c) Nonagricultural substances used in or on processed products, except as other provide in §205.605.

- Chemco Defoamer DF 410 a defoaming agent that is sprayed into the soymilk and filter tank is prohibited. This product contains a nonagricultural ingredient (hydrophobic silica) that is not listed in §205.605; therefore, it is prohibited.
- 3. § 205.303 Packaged products labeled "100 percent organic" or "organic". (b) Agricultural products in packages described in §205.301(a) and (b) must" (2) On the information panel, below the information identifying the handler or distributor of the product and proceeded by the statement, "Certified organic by \*\*\*," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product......"
  - The Rosewood label for the Identify Preserved Soybeans claims the product is certified organic; however, the phrase identifying the certifying agent is not displayed underneath the information for Rosewood.

Section § 205.662(c) of the National Organic Standards state in part: "When correction of a noncompliance is not possible the notification of noncompliance and the proposed suspension or revocation may be combined in one notification." Therefore, the proposed effective date of your revocation is 19 April 2013.

According to §205.662(f)(2): "A certified operation or person responsibly connected with an operations whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, <u>Except</u>, That, the Secretary [of Agriculture] may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility."

If you so choose, you may file an appeal of this Notice of Noncompliance and Proposed Revocation pursuant to §205.681. The appeal should be submitted in writing to : Administrator, USDA, AMS, c/o NOP Appeals Team, STOP 0203, Room 2095-S, 1400 Independence Avenue, SW, Washington, D.C. 20250. <u>The appeal must be filed within **30** days of receipt of this letter</u>.

To better understand the appeals process please visit the USDA National Organic Website at: <a href="http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085659">http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085659</a>

Alternately, you may request mediation pursuant to §205.663. Your request for mediation should be received in this office, in writing, prior to <u>19 April 2013</u>. If we accept your request for mediation and the mediation is successful, you will have 30 days from the termination of mediation to appeal this proposed revocation. If GOA rejects your request for mediation, you will receive a letter from our office, notifying you with a notice of rejection of mediation and information to file an appeal within 30 days of the date of the written notification of mediation rejection.

If you do not request mediation or file an appeal within the timeframes indicated above, the Green Hope LLC dba Rosewood Products certification to the National Organic Program will be revoked for <u>five years</u>. Once revoked your operation will be unable to sell, or label its product as organic.

If you have any questions please feel free to contact me.

Sincerely,

Betty Kananen President/CEO

#### cc: NOP Appeals team - NOPACAAdverseActions@ams.usda.gov

### **Request for Hearing**



### Waiver of Hearing





United States Department of Agriculture Agricultural Marketing Service STOP 0201 – Room 3071-S 1400 Independence Avenue, SW. Washington, D.C. 20250-0201

#### NOTICE TO ALL USDA CERTIFYING AGENTS

- FROM: Barbara C. Robinson, Acting Director National Organic Program
- SUBJECT: Reporting Health & Safety Violations

DATE: February 25, 2009

Effective immediately, certifying agents are obliged to report violations of health or safety to the appropriate local, State, or Federal officials. A copy of all such reporting shall be forwarded to the National Organic Program (NOP) in care of the NOP Compliance and Enforcement Branch (CEB). Further, organic certification shall not be granted or continued when current health or safety inspections have not been granted or renewed for the facility.

The NOP is implementing these requirements under authority of § 205.501 (a) (21) of the NOP regulations—General Requirements for Accreditation.

An organic system plan for every handling facility must have a full description for compliance under § 205.271—the facility pest management practice standard. Under this section, all handling facilities are given various options to prevent pests, including substances on the National List. And if practices in paragraphs (a), (b), (c) and (d) of §205.271 fail, handlers may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations: Provided, *That*, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

Clearly, the regulations in § 205.271 recognize the importance of pest prevention because of the problems that pests can cause—disease and illness. While the NOP is not a health or safety program, no operation can demonstrate compliance with these regulations if the operation fails to comply with the pest management practice standard—that is, the operation exhibits any pest infestation that could lead to a health hazard in that facility.

For example, while we do not expect organic inspectors to be able to detect salmonella or other pathogens, their *potential* sources should be obvious from such evidence as bird, rodent, and other animal feces or other pest infestations.



United States Department of Agriculture Agricultural Marketing Service National Organic Program 1400 Independence Avenue SW. Room 2646-South Building Washington, DC 20250

#### **Policy Memorandum**

To: Stakeholders and Interested Parties
From: Miles McEvoy, Deputy Administrator
Subject: Retained Memo: "Reporting Health & Safety Violations"
Date: Original Issue Date – January 31, 2011

Attached is the "Reporting Health & Safety Violations" memo issued by former Transportation and Marketing Programs Deputy Administrator Barbara C. Robinson on February 25, 2009. This memo is being retained by the NOP as a new policy memo and remains in effect. This document has been assigned the control number "PM 11-6".

Enclosure: "Reporting Health & Safety Violations" February 25, 2009 memo

NOP PM 11-6 Reporting Health & Safety Violations Rev02 10 31 11

Authorized Distribution: Public Page 1 of 1



Global Organic Alliance, Inc.x 5303185 Township Road 179 PO Box 530 Bellefontaine, OH 43311-0530 Phone: 937 593 1232 Fax: 937 593 9507 Email: goaorg@centurylink.net Website: www.goa-online.org

NOV 2 1 2012

# ORGANIC PROCESSOR PLAN Short Form

F

(b)(4)





## Global Organic Alliance, Inc.

P.O. Box 530 3185 Twp Rd 179 Bellefontaine, OH 43311-0530 Phone (937)-593-1232 Fax (937)-593-9507 Email goaorg@centurylink.net Website : www.goa-online.org

22 January 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108

Re: Request for Additional Information

Dear Phil:

Global Organic Alliance (GOA) has reviewed your certification file and is in need of additional information to verify compliance to the <u>National Organic Program (NOP)</u>. Please submit the following:

- 1. §205.406: Inventory records for all organic and nonorganic ingredients and finished products from 9/30/11 to 1/22/13. This is a corrective action from 2011 that has not been resolved.
- 2 §205.301: Nonorganic Ingredient Disclosure Statement for the Magnesium Chloride and Calcium Sulfate completed and signed by the manufacturer. The Nonorganic Ingredients Disclosure Statement submitted with your file is signed by Phil Ye.
- 3. §205.605(b): Verification the magnesium chloride is derived from sea water.
- §205.105: Ingredient information for the defoaming product sprayed into the soymilk tank and into the filter tank. This product is not identified on the Input Log or shown as a processing aid on the Product Composition Sheets.
- \$§205.100, 205.301(b): Verification. Are you repacking soybeans into 30 kg packages and reselling them? A label for "Identity Preserved Soybeans" in 30 kg packages was submitted with the inspection report showing Rosewood Products as the distributor. This handling process was not reported or requested for certification or inspected; therefore, if this is occurring you must submit the appropriate Organic System Plan and supporting documents and undergo an on-site inspection for repacking as this is a different process. This label was not submitted in 2011 and is not compliant with labeling regulations.

Global Organic Alliance must receive a written response and/or requested documentation to the issues listed above by the close of business on <u>5 February 2013</u> so that we may proceed with the certification process without further delay. Failure to respond to this request for additional information will result in adverse action pursuant to §205.662 of the National Organic Program.

Sincerely,

All I week.

Jodi A. Snyder Certification Director














## **GOA Information**

From:Betty Kananen <goaorg@centurylink.net>Sent:Wednesday, February 06, 2013 7:00 PMTo:GOA InformationSubject:Fw: Green Hope LLC/Rosewood - Additional Info for Organic CertificationAttachments:Non\_Org\_Ingredient\_Disclosure\_Calcium Sulfate.jpg;<br/>Non\_Organic\_Ingredient\_Disclosure\_Magnesium Chloride.pdf; Certificate for Nigari.pdf;<br/>Updated\_InputLog\_PrdComposition.pdf

Betty Kananen President/CEO Global Organic Alliance goaorg@centurylink.net Phone - 937.593.1232 Fax - 937.593.9507



----- Original Message -----From: <u>Phil Ye</u> To: <u>goaorg@centurylink.net</u> Sent: Wednesday, February 06, 2013 6:11 PM Subject: Green Hope LLC/Rosewood - Additional Info for Organic Certification

Hello Jody,

I spoke to one lady in your office on Tuesday regarding the additional documentation that we need to submit for our organic certification. I would like to submit some of documents today for your review. Please see below:

1. I'm still working on scanning the documents and will send you the copy before the due date on 2/12/2013.

2. See attached documents signed by the supplier of Magnesium Chloride and Calcium Sulfate.

3. See attached documents from JLS chemical for proving the Magnesium Chloride/Nigari is by product of sea water.

4. See attached for updated input log and product composition sheets.

5. We do not repack the soybeans. Our soybean supplier - did the private labeling for us for marketing purpose.

Let me know if you have further questions. I will be working on #1 and send it over as soon as they are available. Thank you for your assistance.

Best Regards, Phil Rosewood Products

## **GOA Information**

From:Betty Kananen <goaorg@centurylink.net>Sent:Tuesday, February 12, 2013 3:41 PMTo:Brenda McCrearySubject:FW: Rosewood Products organic certification additional info - part 1Attachments:1.1 Organic\_Ingredient\_Inv\_Finish\_Prd\_1.zip

Betty Kananen President/CEO Global Organic Alliance <u>goaorg@centurylink.net</u> Phone – 937.593.1232 Fax – 937.593.9507

From: Phil Ye [mailto:philye@rosewoodproducts.com]
Sent: Tuesday, February 12, 2013 3:35 PM
To: goaorg@centurylink.net
Subject: Rosewood Products organic certification additional info - part 1

Hello Jody,

Here is the requested document for item #1 (I have 3 files in related to item #1, this is 1st file). Due to the large size and the space limit on the email system, I will send you couple of emails. As far as item #2 through #5, I've already responded with several attachments last week. Sorry for the inconvenience and let me know if you have any questions.

Thank you! Phil Rosewood Products 734-665-2222

	DEGEDUED
Free	Global Organic Alliance, Inc. 비민 또 또 또 또 비미
	PO Box 530 3185 Township Road 179
C. M	Bellefontaine, OH 43311-0530
" these ? !	Phone: 937 593 1232 Fax: 937 593 9507
And A	Email: goaorg@centurylink.net Website: www.goa

Responses must be <u>TYPED</u> or <u>HAND WRITTEN LEGIBLY</u> with blue or black ink. Comments and observations MUST be provided to the questions that ask for them. Lack of comments to support your 'yes' or 'no' continues to be an issue and as a result incomplete Inspection Reports will be returned for completion and payment for inspection services will be held. Do NOT RE-SUBMIT DOCUMENTS (I.E. SEED TAGS, INGREDIENT INFORMATION, MAPS, ETC.) THAT WAS SUBMITTED PREVIOUSLY. ONLY SUBMIT INGREDIENT INFORMATION FOR MATERIALS THAT HAVE NOT BEEN SUBMITTED AND/OR REPORTED. NOTE "REVISED" OR "UPDATED" AND THE REVISION DATE ON AMENDED DOCUMENTS (I.E. FIELD HISTORIES, INPUT LOG, MAPS, INVENTORIES, ETC).

HANDLER INSPECTION REPORT			YEAR: 2012		
l	GENERAL INFORMATION		(b)(6),(b)(7)(c),(b)(7)(d)		
	Certification: 🗌 New 🔀 Renewal	Inspection Date: 1/7/2013 Inspec	cio		
	Certification Program: NOP COR EC834/2007 JAS PPM Compliance Program: COR: Is this a transition inspection (at least 12 months prior to certification)? Yes No US/Canada USDA/MAFF				
Type of operation: Processor Handler/Repacker Broker Retail Store Restaurant/Food Service					
Owner/Authorized Representative: Phil Ye and Jessica Tien					
Business Name: Green Hope LLC dba Rosewood Products					
Mailing Address: 738 Airport Boulevard, Suite 6					
ľ	City: Ann Arbor	State/Province: MI	Zip/Postal Code: 48108		
Physical Address: 738 Airport Boulevard, Suite 6					
ĺ	City: Ann Arbor	State/Province: MI	Zip/Postal Code: 48108		
ſ	Phone: 734-665-2222	Cell: (b)(6)	Fax: 734-668-8430		
Email:					
ļ	Legal Status: Sole Proprietorship Partnership Corporation KLLC Cooperative				
Does the operation have the standard(s) applicable to the certification and/or compliance program(s) to which application has been made readily available? X Yes X No If no, what documents are missing?					
	Note: Additional certification and inspection documents are required for JAS and EC 834/2007 certification and compliance verification to the USDA/MAFF Export Arrangement Verification and US/Canada Equivalence Arrangement. USDA/MAFF Export Arrangement Verification is not available to operations outside of the US. If you <b>DID NOT</b> receive completed certification forms CONTACT the GOA office before proceeding.				
I	CONTRACT INFORMATION		Not Applicable – Initial Certification		

CONTRACT INFORMATION			Not Applicable – Initial Certification	
GOA Member Name: 4023P943-09				
Business Name: Green Hope LLC dba Rosewood Products				
Address: 738 Airport Boulevard, Suite 6				
City: Ann Arbor	State/Province: MI		Zip/Postal Code: 48108	
Phone: 734-665-2222	Celi (b)(6)		Fax: 734-668-8430	

(b)(4)











Food Grade Defoamers, Food Processing Defoamer, AntiFoams, Anti-Foam Agents, Def... Page 1 of 1



Potable Water Treatment Chemicals: Corrosion Inhibitors

Degreasers/Cleaners

Distributors:

#### **Betty Kananen**

From: Sent: To: Subject: Attachments: Betty Kananen <goaorg@centurylink.net> Friday, March 22, 2013 3:13 PM 'philye@rosewoodproducts.com' FW: Green Hope Noncompliance adn Revocation 12 Green Hope Noncompliance adn Revocation 12.doc

Betty Kananen President/CEO Global Organic Alliance Boaorg@centurylink.net Phone – 937.593.1232 Fax – 937.593.9507

From: Betty Kananen [mailto:goaorg@centurylink.net] Sent: Friday, March 22, 2013 3:11 PM To: 'rdean@rosewoodproducts.com' Subject: Green Hope Noncompliance adn Revocation 12

Phil,

We did forward your responses to the attached letter to the NOP noncompliance dept, however you are aware that we can do nothing as far as a re review, until you have either requested mediation or filed an appeal with the NOP compliance, please note the highlighted portion in the attached letter.

Just in case you did not realize and thought we were not following through and ignoring you. These are the rules that must be followed.

Betty

## **Betty Kananen**

From:	Betty Kananen <goaorg@centurylink.net></goaorg@centurylink.net>
Sent:	Friday, March 22, 2013 3:11 PM
То:	'rdean@rosewoodproducts.com'
Subject:	Green Hope Noncompliance adn Revocation 12
Attachments:	Green Hope Noncompliance adn Revocation 12.doc

Phil,

We did forward your responses to the attached letter to the NOP noncompliance dept, however you are aware that we can do nothing as far as a re review, until you have either requested mediation or filed an appeal with the NOP compliance, please note the highlighted portion in the attached letter.

Just in case you did not realize and thought we were not following through and ignoring you. These are the rules that must be followed.

Betty



# **Global Organic Alliance, Inc.**

PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530 Phone: 937 593 1232 Fax: 937 593 9507 Email: <u>goaorg@centurylink.net</u> Website: <u>www.goa-online.org</u>

#### SENT VIA: CERTIFIED MAIL RETURN RECEIPT and REGULAR MAIL

12 March 2012

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 USA

#### Subject: Notice of Noncompliance and Proposed Revocation

Dear Phil:

This letter is an official Notice of Noncompliance and Proposed Revocation pursuant to section §205.662 of the USDA National Organic Program Regulations. The proposed revocation is based on noncompliances observed during the on-site inspection of your handling operation in Ann Arbor, MI on January 7, 2013 and response to our request for additional information.

The reason for the proposed revocation is that you failed to comply with the following two sections of the National Organic Program Regulations:

- 1. § 205.400 General requirements for certification. A person seeking to receive or maintain organic certification under the regulations in the part must:
  - (f) Immediately notify the certifying agent concerning any:
    - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.
    - Global Organic Alliance was not notified of the Food and Drug Administration (FDA) proceedings
      regarding Green Hope that have taken place since 2009 and that Green Hope was entering into a consent
      decree of permanent injunction for food safety violations on January 28, 2013 with the FDA. Three-weeks
      to the day of the annual on-site inspection on January 7, 2013 for continued organic certification.
    - Failing to notify Global Organic Alliance of the packaging and private labeling arrangement with
       <sup>(b)(4)</sup> and submitting the Rosewood 'organic' private label for review and approval.
    - Failing to notify Global Organic Alliance of the addition of a defoamer as a processing aid in making the tofu products.
- 2. § 205.105: Allowed and prohibited substances, methods, and ingredients in organic production and handling. To be sold, labeled, or represented as "100 percent organic", "organic", or 'made with organic (specified ingredients or food group(s))," the product must be produced and handled with the use of: (c) Nonagricultural substances used in or on processed products, except as other provide in §205.605.
- Chemco Defoamer DF 410 a defoaming agent that is sprayed into the soymilk and filter tank is prohibited. This product contains a nonagricultural ingredient (hydrophobic silica) that is not listed in §205.605; therefore, it is prohibited.
- 3. § 205.303 Packaged products labeled "100 percent organic" or "organic". (b) Agricultural products in packages described in §205.301(a) and (b) must" (2) On the information panel, below the information identifying the handler or distributor of the product and proceeded by the statement, "Certified organic by \*\*\*," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product......"
  - The Rosewood label for the Identify Preserved Soybeans claims the product is certified organic; however, the phrase identifying the certifying agent is not displayed underneath the information for Rosewood.

Section § 205.662(c) of the National Organic Standards state in part: "When correction of a noncompliance is not possible the notification of noncompliance and the proposed suspension or revocation may be combined in one notification." Therefore, the proposed effective date of your revocation is 19 April 2013.

According to §205.662(f)(2): "A certified operation or person responsibly connected with an operations whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, <u>Except</u>, That, the Secretary [of Agriculture] may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility."

If you so choose, you may file an appeal of this Notice of Noncompliance and Proposed Revocation pursuant to §205.681. The appeal should be submitted in writing to : Administrator, USDA, AMS, c/o NOP Appeals Team, STOP 0203, Room 2095-S, 1400 Independence Avenue, SW, Washington, D.C. 20250. <u>The appeal must be filed within **30** days of receipt of this letter</u>.

To better understand the appeals process please visit the USDA National Organic Website at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085659

Alternately, you may request mediation pursuant to §205.663. Your request for mediation should be received in this office, in writing, prior to <u>19 April 2013</u>. If we accept your request for mediation and the mediation is successful, you will have 30 days from the termination of mediation to appeal this proposed revocation. If GOA rejects your request for mediation, you will receive a letter from our office, notifying you with a notice of rejection of mediation and information to file an appeal within 30 days of the date of the written notification of mediation rejection.

If you do not request mediation or file an appeal within the timeframes indicated above, the Green Hope LLC dba Rosewood Products certification to the National Organic Program will be revoked for <u>five years</u>. Once revoked your operation will be unable to sell, or label its product as organic.

If you have any questions please feel free to contact me.

Sincerely,

Betty Kananen President/CEO

#### cc: NOP Appeals team - NOPACAAdverseActions@ams.usda.gov



## Global Organic Alliance, Inc. PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530 Phone: 937 593 1232 Fax: 937 593 9507 Email: <u>goaorg@centurylink.net</u> Website: <u>www.goa-online.org</u>

#### SENT VIA: CERTIFIED MAIL RETURN RECEIPT and REGULAR MAIL

12 March 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 USA

#### Subject: Notice of Noncompliance and Proposed Revocation

Dear Phil:

This letter is an official Notice of Noncompliance and Proposed Revocation pursuant to section §205.662 of the USDA National Organic Program Regulations. The proposed revocation is based on noncompliances observed during the on-site inspection of your handling operation in Ann Arbor, MI on January 7, 2013 and response to our request for additional information.

The reason for the proposed revocation is that you failed to comply with the following two sections of the National Organic Program Regulations:

- 1. § 205.400 General requirements for certification. A person seeking to receive or maintain organic certification under the regulations in the part must:
  - (f) Immediately notify the certifying agent concerning any:
    - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.
    - Global Organic Alliance was not notified of the Food and Drug Administration (FDA) proceedings
      regarding Green Hope that have taken place since 2009 and that Green Hope was entering into a consent
      decree of permanent injunction for food safety violations on January 28, 2013 with the FDA. Three-weeks
      to the day of the annual on-site inspection on January 7, 2013 for continued organic certification.
    - Failing to notify Global Organic Alliance of the packaging and private labeling arrangement with (b)(4) and submitting the Rosewood 'organic' private label for review and approval.
    - Failing to notify Global Organic Alliance of the addition of a defoamer as a processing aid in making the tofu products.
- § 205.105: Allowed and prohibited substances, methods, and ingredients in organic production and handling. To be sold, labeled, or represented as "100 percent organic", "organic", or 'made with organic (specified ingredients or food group(s))," the product must be produced and handled with the use of: (c) Nonagricultural substances used in or on processed products, except as other provide in §205.605.

- Chemco Defoamer DF 410 a defoaming agent that is sprayed into the soymilk and filter tank is prohibited. This product contains a nonagricultural ingredient (hydrophobic silica) that is not listed in §205.605; therefore, it is prohibited.
- 3. § 205.303 Packaged products labeled "100 percent organic" or "organic". (b) Agricultural products in packages described in §205.301(a) and (b) must" (2) On the information panel, below the information identifying the handler or distributor of the product and proceeded by the statement, "Certified organic by \*\*\*," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product......"
  - The Rosewood label for the Identify Preserved Soybeans claims the product is certified organic; however, the phrase identifying the certifying agent is not displayed underneath the information for Rosewood.

Section § 205.662(c) of the National Organic Standards state in part: "When correction of a noncompliance is not possible the notification of noncompliance and the proposed suspension or revocation may be combined in one notification." Therefore, the proposed effective date of your revocation is 19 April 2013.

According to §205.662(f)(2): "A certified operation or person responsibly connected with an operations whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, <u>Except</u>, That, the Secretary [of Agriculture] may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility."

If you so choose, you may file an appeal of this Notice of Noncompliance and Proposed Revocation pursuant to §205.681. The appeal should be submitted in writing to : Administrator, USDA, AMS, c/o NOP Appeals Team, STOP 0203, Room 2095-S, 1400 Independence Avenue, SW, Washington, D.C. 20250. <u>The appeal must be filed within **30** days of receipt of this letter</u>.

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If you have any questions please feel free to contact me.

Sincerely,

Betty Kananen President/CEO

cc: NOP Appeals team - NOPACAAdverseActions@ams.usda.gov

7011 15700001 5207 6058

Notice of Noncompliance





Natural Foods & Soy Products

Since 1976

From: Rosewood Products Phil Ye/Owner 738 Airport Blvd., Suite 6 Ann Arbor, MI 48108

April 30, 2013

NOP Appeals Team Attn: Mr. Joseph Lloyd 1400 Independence Ave., SW Room 2095-S, Stop 0203 Washington, D.C. 20250

Re: Control Number APL-027-13

Dear Mr. Lloyd,

As per your letter dated on April 8, 2013, I am providing you a copy of the "Notice of Noncompliance and Proposed Revocation" letter sent by Global Organic Alliance dated March 12, 2013. I am also attaching a copy of my appeal letter and supporting documents to demonstrate my company's compliance with the NOP regulations. Please let me know if you have any questions or require further information.

Enclosure:

- 1. Notice of Noncompliance and Proposed Revocation
- 2. Green Hope LLC appeal letter
- 3. Green Hope LLC compliance letter from FDA
- 4. Affidavit

Sincerely,

(b)(b) Phil Ye Owner, Green Hope LLC



April 8, 2013

1400 Independence Ave. SW Room 2095 - South, STOP 0203 Washington, D.C. 20250

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 USA

## Re: Appeal Acknowledgement, APL-027-13

Dear Phil Ye,

This is to acknowledge your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation of National Organic Program (NOP), sent by Global Organic Alliance (GOA). This appeal will be reviewed, heard, and decided by persons not involved with the decision being appealed. Within 30 days of receipt of this letter, please provide the NOP Appeals Team a copy of the Notice of Noncompliance and Proposed Revocation as well as any additional information you believe would support your appeal and demonstrates your compliance with the NOP regulations.

Control Number **APL-027-13** has been assigned to this appeal. Please use this control number on all correspondence regarding this appeal. All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. Sending any correspondence to an incorrect address or by a delivery service that does not adequately provide dated return receipts will jeopardize the procedural status of the appeal and it may be rejected. It is acceptable to submit information by fax or email as wel<sup>1</sup>.

During the appeal process your organic certification status remains valid. As such, any products marketed as organic must meet all regulatory requirements of the NOP. Please note that you must file additional appeals if your accredited certifying agent issues any additional proposed suspensions or proposed revocations.

Sincerely, Joseph Lloyd

NOP Appeals Team 1400 Independence Ave., SW Room 2095-S, Stop 0203 Washington, D.C. 20250 Phone: (202) 720-6766 Fax: (202) 205-5772 NOPAppeals@ams.usda.gov

Cc: Betty Kananen, GOA Miles McEvoy, NOP

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## Global Organic Alliance, Inc. PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530 Phone: 937 593 1232 Fax: 937 593 9507 Email: goaorg@centurylink.net Website: www.goa-online.org

## SENT VIA: CERTIFIED MAIL RETURN RECEIPT and REGULAR MAIL

12 March 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 USA

## Subject: Notice of Noncompliance and Proposed Revocation

Dear Phil:

This letter is an official Notice of Noncompliance and Proposed Revocation pursuant to section §205.662 of the USDA National Organic Program Regulations. The proposed revocation is based on noncompliances observed during the on-site inspection of your handling operation in Ann Arbor, MI on January 7, 2013 and response to our request for additional information.

The reason for the proposed revocation is that you failed to comply with the following two sections of the National Organic Program Regulations:

- 1. § 205.400 General requirements for certification. A person seeking to receive or maintain organic certification under the regulations in the part must:
  - (f) Immediately notify the certifying agent concerning any:
    - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.
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      regarding Green Hope that have taken place since 2009 and that Green Hope was entering into a consent
      decree of permanent injunction for food safety violations on January 28, 2013 with the FDA. Three-weeks
      to the day of the annual on-site inspection on January 7, 2013 for continued organic certification.

Failing to notify Global Organic Alliance of the packaging and private labeling arrangement with (b)(4)
 (b)(4) and submitting the Rosewood 'organic' private label for review and approval.

Failing to notify Global Organic Alliance of the addition of a defoamer as a processing aid in making the tofu products.

2. § 205.105: Allowed and prohibited substances, methods, and ingredients in organic production and handling. To be sold, labeled, or represented as "100 percent organic", "organic", or 'made with organic (specified ingredients or food group(s))," the product must be produced and handled with the use of: (c) Nonagricultural substances used in or on processed products, except as other provide in §205.605.

- Chemco Defoamer DF 410 a defoaming agent that is sprayed into the soymilk and filter tank is prohibited. This product contains a nonagricultural ingredient (hydrophobic silica) that is not listed in §205.605; therefore, it is prohibited.
- 3. § 205.303 Packaged products labeled "100 percent organic" or "organic". (b) Agricultural products in packages described in §205.301(a) and (b) must" (2) On the information panel, below the information identifying the handler or distributor of the product and proceeded by the statement, "Certified organic by \*\*\*," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product......"
  - The Rosewood label for the Identify Preserved Soybeans claims the product is certified organic; however, the phrase identifying the certifying agent is not displayed underneath the information for Rosewood.

Section § 205.662(c) of the National Organic Standards state in part: "When correction of a noncompliance is not possible the notification of noncompliance and the proposed suspension or revocation may be combined in one notification." Therefore, the proposed effective date of your revocation is 19 April 2013.

According to §205.662(f)(2): "A certified operation or person responsibly connected with an operations whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, <u>Except</u>, That, the Secretary [of Agriculture] may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility."

If you so choose, you may file an appeal of this Notice of Noncompliance and Proposed Revocation pursuant to §205.681. The appeal should be submitted in writing to : Administrator, USDA, AMS, c/o NOP Appeals Team, STOP 0203, Room 2095-S, 1400 Independence Avenue, SW, Washington, D.C. 20250. <u>The appeal must be filed within **30** days of receipt of this letter</u>.

To better understand the appeals process please visit the USDA National Organic Website at: <a href="http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085659">http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085659</a>

Alternately, you may request mediation pursuant to §205.663. Your request for mediation should be received in this office, in writing, prior to <u>19 April 2013</u>. If we accept your request for mediation and the mediation is successful, you will have 30 days from the termination of mediation to appeal this proposed revocation. If GOA rejects your request for mediation, you will receive a letter from our office, notifying you with a notice of rejection of mediation and information to file an appeal within 30 days of the date of the written notification of mediation rejection.

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If you have any questions please feel free to contact me.

Sincerely,	
	(b)(6)
Betty Kananen	
President/CEO	

cc: NOP Appeals team - NOPACAAdverseActions@ams.usda.gov

# ROSEWOOD

Natural Foods & Soy Products

Since 1976

From: Rosewood Products Phil Ye/Owner 738 Airport Blvd., Suite 6 Ann Arbor, MI 48108

To: Administrator, USDA, AMS c/o NOP Appeal Team Stop 0203, Room 2095-S 1400 Independence Avenue SW Washington, D.C. 20250

Subject: Re = Notice of Noncompliance and proposed Revocation

To whom it may concern:

My name is Phil Ye. owner of Green Hope LLC dba Rosewood Products. I'm writing in response to the letter dated March 12, 2013 by Global Organic Alliance. Inc in regard to my firm's failed to comply with the National Organic Program Regulations following January 7, 2013's inspection and I wish to appeal the proposed revocation. I am providing you the reasoning and the corrective actions I have taken as follow and in hopes that you will reconsider the proposal of revocation of my firm's organic certification.

1. Non compliance of : 205.400 (f) (2),

- Prior to entering the Consent Decree with FDA, Rosewood had working diligently with NSF International (FDA approved Subject Matter Expert) to addressed all FDA-483 observations. FDA conducted a compliance inspection during October 2013 and concluded that Rosewood had met the FDA regulatory requirements and agreed to issue a notification regarding Rosewood's compliance v.ith the regulations upon signing the Decree (on January 28, 2013). Since there is no change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part, I am not aware that I need to notify the certifying agent. I am attaching a copy of FDA's letter issued on January 28, 2013 for your reference.
- This issue is a miscommunication between Rosewood and Global Organic Alliance Inc. Rosewood had contacted GOA on August 2010 and inquired the procedure of exporting of organic soybean shipment to Taiwan. Rosewood had informed GOA that

(b)(4) would be doing the private label and handling the shipment for Rosewood. GOA had instructed Rosewood to complete a product inventory certificate request (F036), but submitting private label to GOA for approval was never mentioned at the time.



Natural Foods & Soy Products

Since 1976

When I took over Rosewood Products on 2009. I inherited the organic certification, documents and handling plan from previous owners. I have not changed the tofu production process since then. I have personally learned the tofu making process from the previous owner and a long time employee who have worked in this firm and making tofu since 1992. To our knowledge, the use of defoamer is a common process in the tofu making industry during cooking process without knowing the defoaming agent contains nonagricultural ingredient and is not allowed to be used in organic products. I acknowledged this error due to oversight, insufficient knowledge transfer and lack of information.

#### 2.205.105(c)

As mentioned above, upon learning Chemco defoamer DF410 defoaming agent contains a nonagricultural ingredient. I have revised our operating manual and stop using the defoaming agent immediately. In addition, our entire production crew members were informed about this procedure change in our staff meeting held on March 15, 2013. To assure you that I am taking this matter seriously. I am attaching an Affidavit to show that I am responsible and will be personally supervise the new procedure on an on going basis.

#### 3.205.303

Again, as mentioned above, this is a miscommunication between GOA and Rosewood. Upon learning the 'organic private label' has to be submitting to certified agent for review and approval, I have notified (b)(4) to stop producing the Rosewood private label immediately until Rosewood apply for and get approval from GOA.

To that end. I am providing you some background information and hoping the above corrective actions I took will address the noncompliance issues. I have to admit there is a learning curve over the past four years of running this firm, but I continue to make adjustment, correction and seeking ways for improvement as I learn more information. I wanted to let you know that I am taking these issues very seriously. We definitely would follow USDA National Organic Program Regulations in order to stay in compliance; however, sometimes oversight, lack of knowledge training or miscommunication occurs. Please let me know if you have further questions or need additional supporting documents to help us get through the certification process. You could reach me at 734-665-2222 or philye@rosewoodproducts.com.

Thank you very much for your time and consideration of this appeal.

Sinceraly (b)(6)<sup>shy</sup> Phil Ye Owner

3/30/3

738 Airport Blvd., Suite 6, Ann Arbor, MI 48108 • Tel: (734) 665-2222 • Fax: (734) 668-8430 • E-mail: rosewood@mich.com



# DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Detroit District 300 River Place Suite 5900 Detroit, MI 48207 Telephone: 313-393-8100 FAX: 313-393-8139

January 28, 2013

#### VIA EMAIL and UPS

Mr. Phil G. Ye Owner Green Hope, LLC, d/b/a Rosewood Products 738 Airport Blvd., Suite 6 Ann Arbor, MI 48108

## Re: <u>United States of America vs. Green Hope, LLC, d/b/a Rosewood Products</u> and Phil G. Ye, Case No. 2:12-cv-11400-DML-LJM (E.D. Mi.)

Dear Mr. Ye:

The United States Food and Drug Administration ("FDA") inspected your facility in Ann Arbor, MI from October 15-19, 2012. At the close of this inspection, FDA investigators issued to you a three-item Form FDA-483 List of Inspectional Observations. On November 8, 2012, FDA received your letter responding to the October 2012 Form FDA-483. Upon review, the actions described in your response appear adequate to correct the observations noted in the October 2012 Form FDA-483.

As stated in paragraph 4(L) of the Consent Decree for Permanent Injunction ("Decree") in the above-referenced matter, FDA is providing you with written notification that your firm is operating in compliance with paragraphs 4(A) through (I) of the Decree and all applicable FDA regulations. Therefore, you and Green Hope, LLC d/b/a Rosewood Products may continue receiving, processing, manufacturing, preparing, packing, holding, or distributing food at the facility located at 738 Airport Blvd., Suite 6, Ann Arbor, Michigan.

Please note that the other provisions of the Decree remain in effect. FDA will continue to monitor your compliance with all provisions of the Decree, the Federal Food, Drug, and Cosmetic Act ("the Act"), and FDA regulations. If you fail to comply with the Decree, the Act, or FDA regulations, FDA may pursue any and all remedies available to the agency under the Decree and the law. Those remedies include prohibiting you from selling any articles of food (paragraph 9), assessing liquidated damages (paragraph 11), and asking the Court to find you in civil or criminal contempt of the Decree.

Please contact Cicely Vaughn, Compliance Officer, if you have any questions regarding this letter. Ms. Vaughn may be reached by email at <u>cicely.vaughn@fda.hhs.gov</u> or by phone at 313-393-8297.

Sincerely,

Steven Barber Director of Compliance Detroit District Office

ROSEWOOD

Natural Foods & Soy Products

Since 1976

#### AFFIDAVIT

I, Phil Ye, owner of Green Hope LLC, Michigan, MAKE OATH AND SAY THAT:

I have recognized the using of DF410 defoaming agent is prohibited in making organic products after 1 learned from Global Organic Alliance's recent inspection report. I've acknowledge this oversight due to lack of knowledge and training. I've revised our operating manual to stop using DF410 defoaming agent for organic products effective immediately. In addition, our entire production crew members were informed about this procedure change in our staff meeting held on March 15, 2013. The crew members include (b)(6) (Tofu Master) and (b)(6)

Affiant's Signature & Title.

Coner

Firm's Name and Address:
 Green Hope LLC dba Rosewood Products
 738 Airport Blvd. Suite 6
 Ann Arbor, MI 48108

Subscribed and sworn to before me, on the 30 day of Harch. 2013

#### NOTARY PUBLIC



738 Airport Blvd., Suite 6, Ann Arbor, MI 48108 • Tel: (734) 665-2222 • Fax: (734) 668-8430 • E-mail: rosewood@mich.com



'eceived By AMS Compliance 5.8.2013 Initials Date

Natural Foods & Soy Products

Since 1976

## AFFIDAVIT

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Affiant's Signature & Title:

Owner

Firm's Name and Address: Green Hope LLC dba Rosewood Products 738 Airport Blvd. Suite 6 Ann Arbor, MI 48108

Subscribed and sworn to before me. on the 30 day of March, 2013

## NOTARY PUBLIC





#### Natural Foods & Soy Products

Since 1976

From: Rosewood Products Phil Ye/Owner 738 Airport Blvd., Suite 6 Ann Arbor, MI 48108

To: Administrator, USDA, AMS c/o NOP Appeal Team Stop 0203, Room 2095-S 1400 Independence Avenue SW Washington, D.C. 20250

cceived By AMS Compliance Initials

Subject: Re-Notice of Noncompliance and proposed Revocation

To whom it may concern:

My name is Phil Ye, owner of Green Hope LLC dba Rosewood Products. I'm writing in response to the letter dated March 12, 2013 by Global Organic Alliance, Inc in regard to my firm's failed to comply with the National Organic Program Regulations following January 7, 2013's inspection and I wish to appeal the proposed revocation. I am providing you the reasoning and the corrective actions I have taken as follow and in hopes that you will reconsider the proposal of revocation of my firm's organic certification.

1. Non compliance of : 205.400 (f) (2),

- Prior to entering the Consent Decree with FDA, Rosewood had working diligently with NSF International (FDA approved Subject Matter Expert) to addressed all FDA-483 observations. FDA conducted a compliance inspection during October 2013 and concluded that Rosewood had met the FDA regulatory requirements and agreed to issue a notification regarding Rosewood's compliance with the regulations upon signing the Decree (on January 28, 2013). Since there is no change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part, I am not aware that I need to notify the certifying agent. 1 am attaching a copy of FDA's letter issued on January 28, 2013 for your reference.
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ACCEIVED DY **AMS** Compliance 4.8.2013 Initials Date

Natural Foods & Soy Products

Since 1976

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#### 3.205.303

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Thank you very much for your time and consideration of this appeal.

Sincerely. 3/30/13 Phil Ye Owner



April 8, 2013

1400 Independence Ave. SW Room 2095 - South, STOP 0203 Washington, D.C. 20250

Global Organic Alliance (GOA) Betty Kananen PO Box 530 3185 Township Road 179 Bellefontaine, OH 43311-0530

## Re: Appeal Acknowledgement, APL-027-13

Dear Global Organic Alliance (GOA)

This is to acknowledge that Rosewood Products appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation of National Organic Program (NOP), was received by the Administrator on April 8, 2013. This appeal will be reviewed, heard, and decided by persons not involved with the decision being appealed. Within 30 days from receipt of this letter, please provide the NOP Appeals Team with a copy of the documents supporting the Notice of Noncompliance and Proposed Revocation.

Control Number **APL-027-13** has been assigned to this appeal. Please use this control number on all correspondence regarding this appeal. All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. Sending any correspondence to an incorrect address or by a delivery service that does not adequately provide dated return receipts will jeopardize the procedural status of the appeal and it may be rejected. It is acceptable to submit information by fax or email as well.

During the appeal process Rosewood Products's organic certification status remains valid. As such, any products marketed as organic must meet all regulatory requirements of the NOP. Please note that this means that Global Organic Alliance (GOA) must continue to monitor Rosewood Products under the NOP regulations. Please note that Global Organic Alliance (GOA) may issue additional noncompliance notifications; Rosewood Products may file additional appeals if Global Organic Alliance (GOA) issues additional proposed suspensions or proposed revocations.

Sincerely,

Joseph Lloyd

NOP Appeals Team 1400 Independence Ave., SW Room 2095-S, Stop 0203 Washington, D.C. 20250 Phone: (202) 720-6766 Fax: (202) 205-5772 NOPAppeals@ams.usda.gov



April 8, 2013

1400 Independence Ave. SW Room 2095 - South, STOP 0203 Washington, D.C. 20250

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108 USA

## Re: Appeal Acknowledgement, APL-027-13

Dear Phil Ye,

This is to acknowledge your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation of National Organic Program (NOP), sent by Global Organic Alliance (GOA). This appeal will be reviewed, heard, and decided by persons not involved with the decision being appealed. Within 30 days of receipt of this letter, please provide the NOP Appeals Team a copy of the Notice of Noncompliance and Proposed Revocation as well as any additional information you believe would support your appeal and demonstrates your compliance with the NOP regulations.

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Sincerely, Joseph Lloyd

NOP Appeals Team 1400 Independence Ave., SW Room 2095-S, Stop 0203 Washington, D.C. 20250 Phone: (202) 720-6766 Fax: (202) 205-5772 NOPAppeals@ams.usda.gov

Cc: Betty Kananen, GOA Miles McEvoy, NOP



Agricultural Marketing Service 1400 Independence Ave. SW Room 2648 - South, STOP 0268 Washington, D.C. 20250

#### Settlement Agreement

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and Phil Ye, Rosewood Products, and any person responsibly connected with Rosewood Products.

USDA, AMS and Rosewood Products have decided to compromise and settle the issues among them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA) and the USDA organic regulations (7 C.F.R. §§ 205 et seq.).

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- USDA, AMS agrees not to issue a formal Administrator's Decision charging Rosewood Products with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- Rosewood Products, and persons responsibly connected to Rosewood Products, admit to the following:
  - A. Global Organic Alliance, Inc. issued a March 12, 2013 Notice of Non-Compliance and Proposed Revocation to Rosewood Products in Ann Arbor, MI. This Settlement addresses this Notice.
  - B. Rosewood Products has been given the opportunity to appeal the Notice.
  - C. Rosewood Products has been given the opportunity to consult with legal counsel regarding this Settlement.
  - D. Rosewood Products is executing this agreement of its own free will.
  - E. Rosewood Products understands and accepts the terms of this Settlement.
  - F. No alteration or variation of the terms of this Settlement shall be valid unless made in writing and signed by both parties.
  - G. Rosewood Products agrees that failure to comply with the settlement agreement shall automatically void paragraph 2 above, and that USDA, AMS may thereafter continue the formal administrative process, and pursue any and all remedies available under the OFPA and the regulations.

- 4. Rosewood Products, and persons responsibly connected to Rosewood Products, agrees to the following actions:
  - A. Rosewood Products agrees to withdraw its appeal and waives further procedure for the purpose of settling this proceeding and for such purposes only.
  - B. Rosewood Products agrees to pay a civil penalty of \$11,000 in full settlement of this matter.
  - C. Rosewood Products agrees to one unannounced inspection in the next year, in addition to its annual inspection, to be performed by its certifying agent and to be paid for by Rosewood Products.
- 5. Upon execution of this agreement and receipt of the civil penalty payment, the March 12, 2013 Notice of Non-Compliance and Proposed Revocation will be closed.

This agreement will become effective upon execution.

Phil Ye Rosewood Products

Date: 11/8/13Date: 11/12/13

Miles V. McEvoy Deputy Administrator, National Organic Program USDA, AMS



1400 Independence Ave. SW Room 2648 - South, STOP 0268 Washington, D.C. 20250

July 18, 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108

#### **RE: Proposed Settlement Agreement for APL-027-13**

Dear Phil Ye:

The National Organic Program (NOP) Appeals Team has evaluated your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation issued by Global Organic Alliance, Inc. regarding Rosewood Products' NOP certification.

Global Organic Alliance had proposed a revocation of your NOP certification, which would make you ineligible for NOP organic certification for five years. The NOP would like to offer you a settlement agreement that would reduce this penalty to a six month suspension.

A copy of this settlement is enclosed for your consideration. If you agree to the terms, please sign the Agreement, and return the original to the address below within 10 days of receipt of this letter.

You are entitled to consult with an attorney. You may accept or reject this proposed settlement. If you choose to sign and date the settlement agreement, please retain a copy for your files.

If you have any questions, please contact me at <u>Jennifer.Tucker@ams.usda.gov</u> or by phone at 202-260-8077.

Sincerely,

(weller

Jennifer Tucker, Ph.D. Associate Deputy Administrator National Organic Program 1400 Independence Avenue, S.W. Room 2648-S, STOP 0268 Washington, D.C. 20250

cc: Betty Kananen – Global Organic Alliance, Inc.

Enclosure: Proposed Settlement Agreement



Agricultural Marketing Service 1400 Independence Ave. SW Room 2648 - South, STOP 0268 Washington, D.C. 20250

July 26, 2013

Phil Ye Green Hope LLC dba Rosewood Products 738 Airport Blvd, Suite 6 Ann Arbor, MI 48108

#### RE: Follow-up to Request Related to Proposed Settlement Agreement for APL-027-13

Dear Mr. Ye:

Thank you for your call earlier this week concerning the National Organic Program's (NOP) Proposed Settlement to resolve your appeal of the March 12, 2013 Notice of Noncompliance and Proposed Revocation issued by Global Organic Alliance, Inc. regarding Rosewood Products' NOP certification.

During our call, you asked that the NOP reconsider the settlement agreement to remove the six month suspension and potentially replace it with a civil penalty. After reviewing your case again, we have determined that we cannot grant this request. Rosewood used a prohibited substance for an extended period of time in its processing operations; this is a significant violation of the USDA organic regulations. As such, the proposed settlement we offered you on July 18, 2013 stands.

We understand that you may need more time to reconsider the settlement in light of this decision; as such, we are giving you another <u>10 days</u> from receipt of this letter to consider your response. As noted previously, you are entitled to consult with an attorney. You may accept or reject this proposed settlement. If you choose to sign and date the settlement agreement, please retain a copy for your files.

If you have any questions, please contact me at <u>Jennifer.Tucker@ams.usda.gov</u> or by phone at 202-260-8077.

Sincerely,

Jennifer Tucker, Ph.D. Associate Deputy Administrator National Organic Program 1400 Independence Avenue, S.W. Room 2648-S, STOP 0268 Washington, D.C. 20250

National Organic Program (NOP)				
<b>Appeals Case Summary</b>	– Draft Internal Deliberative Document			

Case ID:	APL-027-13	
Operator Name:	Rosewood Products	
Certifier Name:	e: Global Organic Alliance, Inc.	
Preparesd By:	Original: Gilda Villela	
	Revision: Jennifer Tucker	
Date Prepared:	7/8/2013; 9/20/2013	
Adverse Action Being Appealed:	Notice of Non-Compliance and Proposed Revocation	

**Case Summary:** 



1400 Independence Ave. SW Room 2648 - South, STOP 0268 Washington, D.C. 20250

## **Settlement Agreement**

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and Phil Ye, Rosewood Products, and any person responsibly connected with Rosewood Products.

USDA, AMS and Rosewood Products have decided to compromise and settle the issues among them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and regulations promulgated thereunder (7 C.F.R. §§ 205 et seq.).

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to issue a formal Administrator's Decision charging Rosewood Products with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. Rosewood Products, and persons responsibly connected to Rosewood Products, admit to the following:
  - A. Global Organic Alliance, Inc. issued a March 12, 2013 Notice of Non-Compliance and Proposed Revocation to Rosewood Products in Ann Arbor, MI. This Settlement addresses this Notice.
  - B. Rosewood Products has been given the opportunity to appeal the Notice.
  - C. Rosewood Products has been given the opportunity to consult with legal counsel regarding this Settlement.
  - D. Rosewood Products is executing this agreement of its own free will.
  - E. Rosewood Products understands and accepts the terms of this Settlement.
  - F. No alteration or variation of the terms of this Settlement shall be valid unless made in writing and signed by both parties.
  - G. Rosewood Products agrees that failure to comply with the settlement agreement shall automatically void paragraph 2 above, and that USDA, AMS may thereafter continue the formal administrative process, and pursue any and all remedies available under the OFPA and the regulations.

- 4. Rosewood Products, and persons responsibly connected to Rosewood Products, agrees to the following actions:
  - A. Rosewood Products agrees to withdraw its appeal and waives further procedure for the purpose of settling this proceeding and for such purposes only.
  - B. Rosewood Products agrees to a suspension period of six months from the date of settlement execution.
  - C. Rosewood Products agrees that the suspension will continue past the six month suspension period until two conditions are met. First, Rosewood Products must demonstrate to its certifier that the operation is in full compliance with the USDA organic regulations. Second, Rosewood Products must successfully complete the reinstatement process as described at 7 CFR 205.662 Noncompliance Procedures for Certified Operations. Coming into full compliance will allow the certifier and the NOP to consider a request for reinstatement, but does not guarantee reinstatement.
  - D. If and when it is reinstated as a certified organic operation, Rosewood Products agrees to a minimum of one unannounced inspection per year, in addition to its annual inspections, for the next two years, to be performed by its certifying agent and to be paid for by Rosewood Products.
- 5. Upon execution of this agreement, the March 12, 2013 Notice of Non-Compliance and Proposed Revocation will be rescinded.

This agreement will become effective upon execution.

Date: \_\_\_\_\_

Phil Ye Rosewood Products

USDA, AMS

Miles V. McEvoy Deputy Administrator, National Organic Program Date: \_\_\_\_\_



1400 Independence Ave. SW Room 2648 - South, STOP 0268 Washington, D.C. 20250

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USDA, AMS and Rosewood Products have decided to compromise and settle the issues among them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA) and the USDA organic regulations (7 C.F.R. §§ 205 et seq.).

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to issue a formal Administrator's Decision charging Rosewood Products with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
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  - B. Rosewood Products agrees to pay a civil penalty of \$11,000 in full settlement of this matter.
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- 5. Upon execution of this agreement and receipt of the civil penalty payment, the March 12, 2013 Notice of Non-Compliance and Proposed Revocation will be closed.

This agreement will become effective upon execution.

Date: \_\_\_\_\_

Phil Ye Rosewood Products

Date: \_\_\_\_\_

Miles V. McEvoy Deputy Administrator, National Organic Program USDA, AMS



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SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131



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SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131





New Retail Order : Products

## Please enter the quantity for products you wish to add to your order.

Qty SG Gourmet Black Coffee



SereniGy Gourmet Black Coffee will bring your senses to life with the rich smooth flavor and full aroma of the most enjoyable tasting coffee you have ever experienced.

30 Sachets per Box

\$27.00 (USD)

Qty SG Gourmet Mocha Coffee



SereniGy Gourmet Mocha is a dessert in a cup coffee that brings heaven to your mouth as this smooth blend of coffee, cream and cocoa dance with your taste sensations. With the King of Herbs, Organic Ganoderma Blend Extract, added to this cup of bliss, the combination is out of this world!

15 Sachets per Box

\$29.00 (USD)

Qty

SG Gourmet Latte Coffee



SereniGy Gourmet Latte takes the joy of a cup of coffee to a place of ultimate fine taste. We begin with our gourmet black coffee and then bring to life the blended flavor of top quality creamer and sugar to produce a gourmet Organic Ganoderma coffee that you will never forget.

20 Sachets per Box

\$27.00 (USD)

## Qty SG Gourmet Hot Chocolate



SereniGy Gourmet Hot Chocolate is a rich deep blend of the finest cocoa, perfect for relaxing or giving yourself a treat. Kids are especially fond of this beverage as it has won taste tests in 100% of the children tested in 2009.

15 Sachets per Box

\$29.00 (USD)

Qty

SG Organic Green Tea



SereniGy Global Gourmet Organic Green Tea can provide a variety of possible health benefits with pure enjoyment as you experience the deep taste and top quality of this 100% certified organic source of Green Tea together with 100% Certified Organic Ganoderma Blend. Your taste buds will love you after just one sip.

25 Sachets Per Box

\$33.00 (USD)





Certified Organic Rooibos Tea combined with an exclusive and proprietary blend of 100% Certified Organic Ganoderma.

25 Sachets per Box

\$33.00 (USD)

Qty SG Gourmet Chai Tea

SereniGy Global Gourmet Chai Tea is a naturally caffeine-free beverage made with 100% Certified Organic Rooibos Tea, creamer, sugar, and spice combined with an exclusive and proprietary blend of 100% Certified Organic Ganoderma extract.



Qty



SG Ganoderma Essentials

This is 100% Certified Organic Ganoderma herbal capsule.

90 Capsules per Bottle

\$59.00 (USD)

Qty SG Time Capsules



The SG Time Capsule is a unique formula that is based upon years of clinical research and scientific study. Its time you try the most advanced Anti-Aging Ganoderma formula in the world... The SG Time Capsule!

60 Capsules per Bottle

\$99.00 (USD)

Qty

SG Slim Tablets



SG Slim contains exclusive complexes aimed at supporting fat loss through separate mechanisms which are designed to support proper sugar handling, appetite balancing, cellular energy production, and a healthy metabolism.

90 Tablets per Bottle

\$89.00 (USD)

Qty SG Fruit and Veggie Power Plus



SG Fruit & Veggie Power Plus are formulated capsules with a scientific blend of fresh fruit, vegetables & green grass juice extracts, providing a significant increase in concentration of these whole food nutrients resulting in a broad nutritional balancing support for your body all with 100% Certified Ganoderma.

180 Capsules per Bottle

\$74.00 (USD)





SereniGy Global Lightning Capsules are a complement product designed to accelerate the action of the SG 100% Organic Ganoderma Blend nutrients into the cells of your body. These capsules help maximize the effectiveness of Ganoderma in your system.

90 Capsules per Bottle

\$59.00 (USD)










SG Gourmet Mocha Coffee SG Gourmet Latte Coffee SG Gourmet Hot Chocolate SG Organc Green Tea SG Rooibos Tea

SG Gourmet Chai Tea

### \$195.00 (USD)



Qty

SG Tea Combo Pack



1 Box- SG Organic Green Tea

1 Box- SG Rooibos Tea

\$63.00 (USD)



 Bottle- SG Fruit and Veggie Power Plus Capsules
 Bottle- SG Slim Tablets
 Bottle- SG Essential Capsules
 Bottle- SG of Lightning Capsules
 Box- SG Organic Green Tea



\$300.00 (USD)



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Sereni Gy 7

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29 x 25 tea bays Net Wt. 1.76 02 (506) 🤤

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SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Gourmet Rooibos Tea you'll want to

experience on a daily basis.



Bringing Serenity, Energy, Integrity and 100% Cer Organic Ganoderma Through You Around the Glo

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Company

Products

Training

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Shop/Enroll

Virtual Office

# **Top 20 LPP-Month of August**

Abuga, Amos
MOORE, JAME
Barragan, Irma
Murdoch, Brai
Bell, Terry
Price, Caron
Carvajal, Maricella
Pritchard, Jos
CASBIS, ABEL
Smith, Emma
Dinka, Drusilla
Thompson, Da

http://serenigy.com/pages.aspx?id=71

	Henry, Derek and Michelle	🕨 Veazia, Laura
	Marley, Danielle	Wilkerson, Va
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SereniGy Global Inc



### Corporate Overview

SG Promotions

SG Market Place

Login to Virtual Office



#### Welcome to SereniGy

Imagine you being able to be placed right in the epicentre of one of the fastest growing industries on a Global scale?

Imagine marketing a universal product that needs NO explanation and the masses have a habit of consuming? What if we told you that we are combining two Mega Industries to allow you the chance of a lifetime to sit at the front of a movement that will forever revolutionize the way consumers will look at these 2 Mega Trends!

#### The SG Movie



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bring your senses to life with the rich smooth flavor and full aroma of the most enjoyable tasting coffee you have ever experienced. This pre-brewed gourmet beverage provides the best coffee has to offer without sugar or any artificial additives. The special nutrient that makes this coffee stand above all the rest is the proprietary blend of the world-renowned "King of Herbs" Organic Ganoderma Blend Extract.

SereniGy Gourmet Black Coffee will

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SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131





November 15, 2010

Mr. Jay Noland SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: NOP Complaint Case Number NOPC-005-11

Dear Mr. Noland:

The U.S. Department of Agriculture (USDA) National Organic Program (NOP) has received a complaint alleging that your company markets its products with the term "100% certified organic" on the front panel without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a USDA accredited certifying agent and must comply with the Code of Federal Regulations: 7 CFR Part 205, National Organic Program.

Please contact me within 5 days of receipt of this letter to discuss the complaint. I can be reached at (202) 205-5213 and renee.mann@ams.usda.gov.

Thank you for your attention to this matter.

Sincerely,

Renee Mann Compliance Specialist NOP



Agricultural Marketing Service

1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

December 1, 2010

Mr. Jay Noland SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: NOP Complaint Case Number NOPC-005-11

Dear Mr. Noland:

The U.S. Department of Agriculture (USDA) National Organic Program (NOP) has received a complaint alleging that your company markets its products with the term "100% certified organic" without certification of the final product, which is a violation of the NOP regulations. Specifically, the following violations have been identified:

- 1. Claims of "with 100% Certified Organic Ganoderma Extract" on the front panels of SereniGy's Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate, and Gourmet Chai Tea
- Claims of "100% Certified Organic Green Tea" and "100% Certified Organic Rooibos Tea" on the SereniGy Global Gourmet Organic Green Tea and SereniGy Global Gourmet Organic Rooibos Tea, respectively, in addition to claims of "with 100% Certified Organic Ganoderma"
- Claims of "100% Certified Organic Ganoderma" used on the Neutraceuticals products: SG Ganoderma Essential, SG Time Capsule, SG Slim, SereniGy Fruit & Veggie Power Plus, SG Lightning
- 4. Statements of "100% Certified Organic" in reference to various products that are not certified on the SereniGy website.

The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a USDA accredited certifying agent. Also, all such agricultural commodities must comply with the Code of Federal Regulations: 7 CFR Part 205, National Organic Program.

Please be advised that failure to <u>cease and desist</u> use of the term "organic" and "certified organic" on the SereniGy product labels when SereniGy does not have organic certification and failure to comply with the NOP regulations may result in a civil penalty of \$11,000 per violation.

Noland, pg. 2

I previously sent a letter to your office on November 15, 2010, from which I have not received a response. Please contact me immediately upon receipt of this letter to discuss the complaint. I can be reached at (202) 205-5213 and <u>renee.mann@ams.usda.gov</u>. Thank you for your attention to this matter.

00339

Sincerely,

Ra he

Renee Mann Compliance Specialist NOP

- <u>Home</u>
- •
- <u>Opportunity</u>
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- Fundraising Program
  - <u>How it Works</u>
  - Get Started
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- CJM Schedule
- •
- <u>Contact Us</u>
- •
- <u>Blog</u>

<u>Ms. Atavia Louis</u> <u>Global Coffee Broker</u> <u>510-593-4000</u> <u>Oakland, CA 94606</u>

Your Name (required)

Your Email (required)

Phone Number (required)

Subject

Your Message

Send

00340

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- Fundraising Program
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- <u>CJM Schedule</u>
- <u>Contact Us</u>
- o <u>Blog</u>

The Java Blog

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- <u>Featured</u>
- <u>News</u>
- <u>Opportunity</u>
- <u>Uncategorized</u>

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- <u>SG Heat</u>
- Shop & Enroll

"Got Healthier Coffee?" **Independent Coffee Brokers SereniGy Global, Inc.** Stay Connected Subscribe to my blog for updates

Name:	
Email:	
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SG Heat Conference Call

# Join the SG Heat Daily Conference call.

Every Monday - Friday 11amPST/ 2pmEST Phone: 605-475-6400 Pin 5877633#

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Website Design and Marketing by Big City Solutions

<u>Sitemap</u>

[fname],

### LIVE FROM MAUI, HAWAII!

Our CEO, Mr. Jay Noland, will be hosting a very special SG Heat Call LIVE from Maui, Hawaii!

Make sure to spread the word to every one you know.

Call Details:

Date: 12/6/2010 (wed)

Time: 2PM EST

Ph.#: 605-475-6400 Pin 5877633#

We look forward to hearing you on the call. This is going to be HOT!

Sincerely, SG Staff

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- CJM Schedule
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- <u>Contact Us</u>
- •
- <u>Blog</u>

<u>Ms. Atavia Louis</u> <u>Global Coffee Broker</u> <u>510-593-4000</u> <u>Oakland, CA 94606</u>

Your Name (required)

Your Email (required)

Phone Number (required)

Subject

Your Message

Send

00343

# Abundantly Java!

- o <u>Home</u>
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Resources

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Name:	
Email:	
Submi	t

SG Heat Conference Call

# Join the SG Heat Daily Conference call.

Every Monday - Friday 11amPST/ 2pmEST Phone: 605-475-6400 Pin 5877633#

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<u>Sitemap</u>

Oriental Super-Mart 7854 Wiles Road Coral Springs, FL 33067 954-501-8601 If you have any questions regarding these Store Policies, please contact our Customer Service at our email address: orientalsupermrk@bellsouth.net Or 1-954 501-8601 during n	ormal	
Contact Us	Jima	
	information	
Email Address: * Message: *		
	*	
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- our Story
- <u>contact Us</u>

# The Silver Lining

Upgrading your *health* through *gourmet coffee* and *ganoderma* 

# **Contact Us**

We'd love to hear from you! Whether you have a question about the products or the business opportunity, we will get back to you in typically 1-2 business days.



Share

Your Name (required) Renee Mann

Your Email (required) renee.mann@ams.usda.gov

Subject

Organic Certifier

Your Message

```
Dear Derek and Michelle,
```

I am writing regarding the organic certification of the SereniGy products. Can you please tell me who the products are certified by? Specifically, the organic green tea, rooibos tea, and chai tea appear to have the "certified by... " statement on the side panel of the box.

Send

Derek and Michelle Henry, Serenigy Global Independent Distributors

# <u>Coffee Comparison</u>

See what your coffee is missing

• <u>FAQ'S'</u>

Need more answers? Get them here.

• Enroll

Get started or get product at wholesale today!

<u>Audio/Video Vault</u>

Visual person? Check this out.

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Unlocking the code to nutrition and making health simple.

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- <u>the Opportunity</u>
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- <u>our Story</u>
- <u>contact Us</u>
- Derek and Michelle Henry, Serenigy Global Independent Distributors

Powered by ganoderma

### Re: SereniGy, NOP Complaint Case Number NOPC-005-11

Dear Dr. Bartell,

It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code of Federal Regulations, 7 CFR §205, National Organic Program.

Specifically, the complaint alleges that the Gourmet Black Coffee and Gourmet Latte are not certified as organic. Additionally, I have identified several other products on your website that may have labeling violations, which we discussed.

Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create labels that are compliant with the regulations. Pay specific attention to §205.100 *What has to be certified*, §205.101 *Exemptions and exclusions from certification* and Subpart D-Labels, Labeling, and Market Information.

http://ecfr.gpoaccess.gov/cgi/t/text/text-

idx?c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7

If the above link does not work, you can also navigate to the regulations through the NOP website's Resource Center: <u>http://www.ams.usda.gov/NOPResourceCenterRegulations</u>

In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010:

- 1. Submit the current product labels, including information and display panels, for the following products:
  - a. Gourmet Black Coffee
  - b. Gourmet Latte
  - c. Gourmet Mocha
  - d. Gourmet Hot Chocolate
  - e. Gourmet Chai Tea
  - f. Organic Green Tea
  - g. Gourmet Organic Rooibos Tea
  - h. SG Ganoderma Essential
  - i. SG Time Capsule
  - j. SG Slim
  - k. SereniGy Fruit & Veggie Power Plus.
- 2. Submit revised labels for the abovementioned products that are compliant with the NOP regulations.

- 3. Revise the abovementioned labels on the website, and ensure that references to "organic" products or ingredients are in compliance with the NOP regulations.
- 4. Identify the manufacturer of the abovementioned products that processes and labels the finished product.
- 5. Submit the organic certificate of the ganoderma that is used in the SereniGy products.
- 6. Provide a proof of purchase of the ganoderma (by the manufacturer identified in number 3 above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4)(iii) records must be maintained by the exempt handling operation).
- 7. Confirm that the Nutraceutical *SG Lightning* does not claim "organic" on its label. You could meet this requirement by submitting the current product label.

If you have any questions, please feel free to contact me at (202) 205-5213 or <u>renee.mann@ams.usda.gov</u>. Also, please note that I will be on vacation from December 20<sup>th</sup> through December 25<sup>th</sup>. If I am unavailable, you may contact a representative of the NOP through the main NOP phone line at (202)720-3252.





Re: SereniGy Global Inc., NOP Complaint Case Number NOPC-005-11





Should you have any questions regarding this matter, you may contact Renee Mann, Compliance & Enforcement, at 202-205-5213 or renee.mann@ams.usda.gov.

Sincerely,

Mark Bradley Director, Compliance and Enforcement Division National Organic Program

- 1. Submit the current product labels, including information and display panels, for the following products:
  - a. Gourmet Black Coffee Received.
  - b. Gourmet Latte Received box.
  - c. Gourmet Mocha Received box.
  - d. Gourmet Hot Chocolate Received.
  - e. Gourmet Chai Tea Received box.
  - f. Organic Green Tea Received box.
  - g. Gourmet Organic Rooibos Tea Received box.
  - h. SG Ganoderma Essential Received.
  - i. SG Time Capsule Received.
  - j. SG Slim Received.
  - k. SereniGy Fruit & Veggie Power Plus. Received.
- 2. Submit revised labels for the abovementioned products that are compliant with the NOP regulations.
  - a. Gourmet Black Coffee Received.
  - b. Gourmet Latte Received.
  - c. Gourmet Mocha Received.
  - d. Gourmet Hot Chocolate Received.
  - e. Gourmet Chai Tea Received box.
  - f. Organic Green Tea
  - g. Gourmet Organic Rooibos Tea
  - h. SG Ganoderma Essential Received.
  - i. SG Time Capsule Received.
  - j. SG Slim Received.
  - k. SereniGy Fruit & Veggie Power Plus. Received.
- 3. Revise the abovementioned labels on the website, and ensure that references to "organic" products or ingredients are in compliance with the NOP regulations.
  - a. Gourmet Black Coffee. Proposed label does not seem compliant; the term "100% Certified" is misleading.
  - b. Gourmet Latte Proposed label does not seem compliant; the term "100% Certified" is misleading.
  - c. Gourmet Mocha Proposed label does not seem compliant; the term "100% Certified" is misleading.
  - d. Gourmet Hot Chocolate Proposed label does not seem compliant; the term "100% Certified" is misleading.
  - e. Gourmet Chai Tea Proposed label does not seem compliant; the term "100% Certified" is misleading.
  - f. Organic Green Tea. Label is acceptable (same as the one NDA provided to me).
  - g. Gourmet Organic Rooibos Tea. Label is acceptable (same as the one NDA provided to me).
  - h. SG Ganoderma Essential. Current label is produced by a certified operation, but not approved by QAI. It is 100% with a non-certified, non-organic vegetable capsule. Revision is needed to remove references to certification and QAI.
  - i. SG Time Capsule. Same as Essential above.
  - j. SG Slim. Current label is produced by a certified operation, but I am not sure if it was approved by QAI. It is not 100% organic, but the label carries the claim "with 100% certified organic ganoderma." Revision is needed, whether or not it is certified. Proposed label is acceptable.

- k. SereniGy Fruit & Veggie Power Plus. Current label carries USDA Organic seal. Proposed label is acceptable because it does not use the USDA seal.
- 4. Identify the manufacturer of the abovementioned products that processes and labels the finished product. Received.
- 5. Submit the organic certificate of the ganoderma that is used in the SereniGy products. Inadequate. But QAI did confirm that the ganoderma is certified through several conversations. Received certificate from QAI.
- 6. Provide a proof of purchase of the ganoderma (by the manufacturer identified in number 3 above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4)(iii) records must be maintained by the exempt handling operation). Submitted proof of purchase for 18 GanoUltra<sup>™</sup> Full Spectrum Myco Product, USDA Certified Organic, Lot #GL170210.
- 7. Confirm that the Nutraceutical *SG Lightning* does not claim "organic" on its label. You could meet this requirement by submitting the current product label. Submitted label. Label does not use the term organic and is therefore not within the NOP's scope.

Dear Renee,

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

**Lightning:** No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification.

**Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim:** These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site.

Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

### SereniGy Product Manufacturers: (Confidential Information)



Dear Dr. Bartell,

Thank you for submitting your response to the NOP regarding your various product labels that identify organic ingredients.

I have been in communication with Quality Assurance International (QAI) regarding the Time, Essential, and Slim labels. QAI issued a cease and desist notification to you because your labels cannot carry the QAI logo if your final product is not certified by QAI. To clarify, in order to display the USDA seal, the words "certified organic" or the QAI logo, the entire product would need to be certified as organic by QAI. Because only the ganoderma in the product is certified and the entire product is not certified, you cannot use the "certified organic" label claim, USDA seal or QAI logo. The finished product is certified only by being produced in an organic certified facility by a company that carries certification AND if the product labels have been reviewed and approved by the certification agency, such as QAI.

Please revise the supplement labels that contain references to QAI by removing the QAI logo and any reference to QAI. You can still obtain certification for these products in the future, but for the time being because the products are not certified, the labels must not display the QAI logo. To obtain certification, your supplier or you may work directly with a certifier, such as QAI, to obtain approval for the labels.

In relation to the Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate and Gourmet Chai Tea, the term "100% Certified" on the principal display panel (front panel) appears to reference the organic certification of the ganoderma ingredient. This is a violation of 7 CFR §205.100 and §205.305(a) because the claim could mislead customers to think that the entire coffee or tea product is 100% certified. Only products that are certified may be represented as organic on the principal display panel. Please revise these labels again to remove the term "certified" and submit proofs to me for review.

Thank you for providing the proof of purchase of the (b)(4) ganoderma product. In relation to your other manufacturers, please identify from what company the ganoderma is purchased that is subsequently used by (b)(4) and (b)(4) to manufacture the Serenigy products. QAI confirmed that (b)(4) carries certification for its ganoderma product but I need to confirm that the ganoderma going into all of your products is certified. If there is another source besides (b)(4) please provide the certificates for the additional ganoderma products and the proofs of purchase.

Please provide your response by February 18, 2011. If you have any questions, feel free to contact me at (202) 205-5213 or <u>renee.mann@ams.usda.gov</u>.

Sincerely,

Renee Mann



### CASE CLOSURE MEMORANDUM

- TO: Mark Bradley Director NOP Compliance and Enforcement Division
- FROM: Renee Mann Compliance Specialist NOP Compliance and Enforcement Division
- SUBJECT: NOPC-005-11 SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

CERTIFYING AGENTS INVOLVED: Quality Assurance International, Nevada Department of Agriculture

COMPLAINANT: (b)(6),(b)(7)(c),(b)(7)(d)

ALLEGED VIOLATION: SereniGy Global Inc., produces products that do not have either a manufacturer or a certification agency listed on the packaging. The packaging states "100% certified organic" in violation of the NOP regulations.

SUMMARY: Nine of SereniGy's products are in violation of §205.100(a) because they are not certified. The company representative, Dr. BARTELL, explained his company's understanding of the NOP regulations, which is incorrect. The ganoderma (mushroom) ingredient in the products is 100 % certified organic, which SereniGy thought allowed it to make claims of "with 100% certified organic ganoderma" on its product labels.

SereniGy is in the process of making corrective actions to bring its products into compliance with the NOP regulations. For more information, see the Report of Investigation.

ACTION REQUESTED: Approval is requested to close case.

APPROVED FOR CLOSURE BY:

Mark Bradley

Date



# VIA EMAIL



Re: SereniGy Global, Inc., Complaint Case NOPC-005-11

	(b)(6	(7)(c)	,(b)(7)	
Dear	(d)			

The Department of Agriculture (USDA) National Organic Program (NOP) has concluded its investigation of the complaint you filed against SereniGy Global, Inc. (SereniGy) on October 14, 2010. Your complaint alleged that SereniGy produces products that do not have either a manufacturer or a certification agency listed on the packaging.

Our investigation indicated that SereniGy produces two 100% certified organic products with current organic certification through the Nevada Department of Agriculture. These two products are the rooibos and green teas. Our investigation also indicated that several other SereniGy products, including the black coffee and latte that you specifically referenced in the complaint, are not certified organic and make various "organic" claims on the labels, in violation of the NOP regulations. SereniGy has been notified of the violations and is in the process of removing the "organic" claims from some of its labels and obtaining certification for some of its products.

Thank you for bringing this matter to our attention. We appreciate your support of the NOP and the USDA. The case is hereby closed.

Sincerely,

Miles McEvoy Deputy Administrator National Organic Program



# VIA EMAIL

Dr. Kent Bartell SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: SereniGy Global, Inc., Complaint Case NOPC-005-11

Dear Dr. Bartell:

The Department of Agriculture (USDA) National Organic Program (NOP) has completed its review of Serenigy Global, Inc.'s (SereniGy) responses to the investigation of the complaint filed against your company on October 14, 2010. The NOP determined that nine of the SereniGy product labels are in violation of the NOP regulations (Code of Federal Regulations, Title 7 Part 205).

Specifically, the following five products, which are not certified organic, claim "100% certified organic ganoderma," which is a violation of §205.100(a) of the NOP regulations: Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate, and Gourmet Chai Tea. The following four products, which are not certified organic, claim "100% certified organic" or "with 100% certified organic ganoderma" on the front panel of the labels and use the USDA organic seal on the back panel of the labels, which is a violation of §205.100(a) and §205.311: Essential, Time Capsule, Slim, and Fruit & Veggie Power Plus.

We are aware that SereniGy plans to obtain certification for several of its supplements and to remove the organic claims that violate the NOP regulations from the remaining labels. Full implementation of these corrective actions will be verified through future market surveillance by the NOP. Please be advised that failure to <u>cease and desist</u> use of the term "organic" and use of the USDA seal on product labels in violation of the NOP regulations may result in a civil penalty of \$11,000 per violation.

If you have questions please feel free to contact Renee Mann with the Compliance & Enforcement Division at (202) 205-5213 or renee.mann@ams.usda.gov.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program



# Report of Investigation

# UNITED STATES DEPARTMENT OFAGRICULTURE NATIONAL ORGANIC PROGRAM COMPLIANCE & ENFORCEMENT DIVISION

Complaint Number:

NOPC-005-11

Complainant Name & Address:

(b)(6),(b)(7)(c),(b)(7)(d)

Operator Name & Address:

SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Accredited Certifying Agent Name & Address:

Nevada Department of Agriculture 405 S. 21st St. Sparks, NV 89431

Date of Complaint:

October 14, 2010

Allegations: SereniGy Global Inc., produces products that do not have either a manufacturer or a certification agency listed on the packaging. The packaging states "100% certified organic" in violation of the NOP regulations.

Relevant Regulations: Code of Federal Regulations, Title 7 Part 205, National Organic Program. Specifically, §205.100(a) *What has to be certified* and §205.301(a) and (c) *Product composition*.

Date of Investigation:	November 1, 2010 to February 22, 2011
Date of Report:	March 4, 2011
Compliance Specialist:	Renee Mann

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### REPORT OF INVESTIGATION TABLE OF CONTENTS

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# REPORT OF INVESTIGATION:

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- II. ALLEGATIONS
- III. METHODOLOGY
- IV. FINDINGS OF FACTS
- V. CONCLUSION & RECOMMENDATION

# EXHIBITS

- 1. ORIGINAL COMPLAINT
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- 3. LABELS
- 4. First written contact attempt
- 5. Second written contact attempt
- 6. Third written contact attempt
- 7. Confirmation of certification by Nevada Department of Agriculture (NDA)
- 8. First information request to SereniGy's Dr. Bartell
- 9. Information submission from NDA
  - a. Product profiles
  - b. Current, revised labels
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- 11. Certificate  $-^{(b)(4)}$
- 12. Information submission from Quality Assurance International (QAI) confirming that the supplements are not certified
- 13. Information submission from <sup>(b)(4)</sup> confirming that they are not responsible for uncertified product carrying the USDA seal.
- 14. Second information request to SereniGy's Dr. Bartell
- 15. SereniGy statement: it buys all of its ganoderma from (b)(4)
- 16. SereniGy statement: it is seeking certification for its supplement labels
- 17. LABELS (second, final revision)
# REPORT OF INVESTIGATION

# I. INTRODUCTION

The Compliance & Enforcement (C&E) Division of the National Organic Program (NOP) is responsible for investigating complaints filed under the Organic Foods Production Act of 1990 (7 USC 6501 et seq.) and its related laws and regulations.

On October 14, 2010, C&E received a complaint through the NOPCompliance@ams.usda.gov email inbox. An investigation was conducted and the results of the investigation are contained in this report.

The investigation was conducted by gathering information from the manufacturer, SereniGy Global, Inc (SereniGy). Also, information was gathered from Nevada Department of Agriculture (NDA), which is the certifier of several of the SereniGy products. Finally, information was gathered from Quality Assurance International (QAI), which certifies the ganoderma ingredient that is used in the SereniGy products.

# II. ALLEGATIONS (b)(6),(b)(7)(c)

The complaint was filed by against SereniGy. The specific allegation is that the SereniGy products Gourmet Black Coffee and Gourmet Latte packaging state "100% certified organic" but do not disclose a manufacturer or a certification organization (exhibit 1).

# III. METHODOLOGY

Renee MANN was assigned to investigate the complaint. She began the investigation by attempting to gather documentation from SereniGy. MANN had difficulty finding contact information for SereniGy and sent two letters to the company's physical address with no response (exhibits 4 and 5). SereniGy is a multi-level marketing (MLM) company with numerous independent vendors of its products. MANN called several of SereniGy's vendors; through these contacts she obtained an email address to a SereniGy executive. MANN emailed several SereniGy executives (exhibit 6) and was ultimately contacted by a different executive: Dr. BARTELL. BARTELL was cooperative throughout the investigation.

MANN also contacted the two certifiers associated with the company. Both NDA and QAI were asked to clarify whether SereniGy's beverages and supplements were certified. Both certifiers cooperated with the investigation by providing the current labels and other documentation regarding SereniGy's products and the certified organic ganoderma ingredient.

# IV. FINDINGS OF FACT

The SereniGy website advertises various coffees, teas, and supplements with claims of "organic" and "100% certified organic" in numerous locations on the product labels and in the language describing the products (exhibit 2). All of the products that claim some amount of organic content contain a certified organic ganoderma (mushroom) ingredient. Specifically, the labels on the SereniGy website (exhibit 3) display the following statements:

- Claims of "with 100% Certified Organic Ganoderma Extract" on the front panels of SereniGy's Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate, and Gourmet Chai Tea
- 2. Claims of "100% Certified Organic Green Tea" and "100% Certified Organic Rooibos Tea" on the Gourmet Organic Green Tea and Gourmet Organic Rooibos Tea, respectively, in addition to claims of "with 100% Certified Organic Ganoderma."
- 3. Claims of "100% Certified Organic Ganoderma" used on the Nutraceuticals products: Essential, Time Capsule, Slim, and Fruit & Veggie Power Plus.
- 4. Statements of "100% Certified Organic" in reference to various products that are not certified on the SereniGy website.

BARTELL confirmed that two of the SereniGy products, the organic rooibos tea and organic green tea, are certified by NDA (exhibit 7). He also explained that the coffee products, chai tea, and supplements are not certified organic products, but that each product contains certified organic ganoderma. He noted that the Lightning product does not contain any organic content and does not make any organic claims on the label of the product.

MANN asked BARTELL to submit the current labels for the products that use the term "organic" on their labels (exhibit 8) and contacted NDA. NDA responded to MANN by stating that the rooibos and green teas were indeed certified organic products produced under a private label agreement (exhibit 9) and that the products contained organic ganoderma that is certified by QAI (exhibit 9a). NDA provided the current labels for the products (exhibit 9b), which NDA approved on March 25, 2010, and the previous labels that NDA found to be in violation of the NOP regulations (exhibit 9c).

BARTELL responded to the investigation by submitting a written explanation of the organic components of each product, an explanation of which products are certified (exhibit 10), a proof of purchase for the certified organic ganoderma (exhibit 10a), and the current and proposed labels for the products (exhibit 10b). MANN contacted QAI to confirm that the ganoderma was certified by QAI and to determine whether the four supplement labels that contain the QAI logo (Essential, Time Capsule, Slim, and Fruit & Veggie Power Plus) are certified by QAI. QAI responded that these products are not certified organic (exhibit 12) and are produced at a different facility that (b)(4) claims is certified (exhibit 13). QAI also confirmed that the ganoderma, which is produced by (b)(4) is certified organic (exhibit 13).

Following these interactions, MANN informed BARTELL that his suggested labels for several products were still in violation of the NOP regulations. Specifically, the coffees and tea that were not certified still contained the word "100% certified ganoderma" in place of "100% certified

organic ganoderma" on the front packaging; the NOP found both wording choices to be unacceptable. She also informed him that the supplements could not use the QAI logo if they were not certified organic (exhibit 14). BARTELL confirmed that he was in the process of getting three of the four supplements certified by QAI (exhibit 15) and he submitted revised labels (exhibit 17), which are in compliance with the NOP regulations. He noted that the revised supplement labels would be used when purchasing new labels from <sup>(D)(4)</sup> (exhibit 16). BARTELL did not mention when the other product labels would be revised for the coffees, tea, and one supplement, because he had asked for approval from the NOP before printing these labels.

# V. CONCLUSION & RECOMMENDATION

The complainant's allegation contained two parts: 1) that the products do not disclose a manufacturer and 2) that the products claim certification without being certified organic. The NOP regulations do not require that the product's manufacturer be disclosed on the label. However, the NOP determined that nine products produced by SereniGy are in violation of the NOP regulations because they are not certified organic but they contain various claims of "certified organic."

The following five products, which are not certified organic, claim "100% certified organic ganoderma" on the front panel of the labels:

- 1. Gourmet Black Coffee
- 2. Gourmet Latte
- 3. Gourmet Mocha
- 4. Gourmet Hot Chocolate
- 5. Gourmet Chai Tea

The following four products, which are not certified organic, claim "100% certified organic" or "with 100% certified organic ganoderma" on the front panel of the labels and use the USDA organic seal on the back panel of the labels:

- 6. Essential
- 7. Time Capsule
- 8. Slim
- 9. Fruit & Veggie Power Plus

<u>Regulatory References</u>: 7 CFR Part 205, National Organic Program regulations require that most food products that use the term "organic" be certified. Specifically, §205.100(a) *What has to be certified* specifies that products intended to be sold, labeled or represented as "100percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of the NOP regulations with certain exceptions for excluded and exempt operations. Section 205.301(a) and (c) specify the organic and non-organic composition of products labeled as "100 percent organic" and "made with organic (specified ingredients or food group(s))." Section 205.311 notes that the USDA seal can only be used in conjunction with products that are certified organic. Page 5 of 6

### Recommendation

SereniGy's nine products are in violation of §205.100(a) because they are not certified. BARTELL explained that his company's understanding of the regulation was that only certified products could use the USDA seal, which is why the rooibos and green teas use the USDA seal and the supplements that SereniGy purchases as private label products through a certified operation, (b)(4) use the USDA seal as well. For the products that BARTELL fully admitted were not certified, SereniGy assumed that the products were acceptably labeled as "with 100% certified organic ganoderma" because the ganoderma used in the SereniGy products is 100% certified organic by QAI. Therefore, SereniGy asserts that it made a truthful statement that the products contained a certified ingredient.

SereniGy is in the process of getting its supplements certified organic through QAI and plans to change its uncertified product labels to remove the "certified organic" statements (exhibit 10b). C&E recommends sending a cease and desist letter to SereniGy, which explains the violations of the NOP regulation on each SereniGy label and warns that the company may be fined \$11,000 per future violation. This company is an appropriate candidate for future surveillance of its labels to determine that it followed through with certification and changing its labels.

Hello Renee,

I have re-submitted the Slim, Time and Essential labels to you through (b)(4) yesterday as per your request as a "cc" with our submission to QAI. Today I have also sent you 6 revised graphic files which were the corrected Fruit & Veggie Label, Black coffee, Latte coffee, Mocha coffee, Hot Chocolate, and the Chai Tea for your review. Please confirm receipt of these emails or if you have any further questions regarding our compliance.

Thank you and have a great day,

Dr. Bartell



# **Organic Certification**

TO: SereniGy Global, Inc. 201 S. Biscayne Blvd. Suite 2800 Miami, FL 33131 DATE: November 2, 2011

Lot Number:
122 12
Various

Serenigy global products contain USDA 100% certified organic Ganoderma – we have received adequate documentation in the form of Organic certification from the growers/producers and batch records demonstrating the incorporation of these material into numerous SereniGy Global products.

Dinesh Patel, Ph.D. Laboratory Director

This Report is issued in accordance with the Standard Terms and Conditions including but not limited to our services and reports (i) are for the benefit of the client only and may not be used by any other party for any purpose and (ii) relate solely to the sample(s) in our possession and cannot be applied to any other material.



1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

### Settlement Agreement

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and SereniGy Global, Inc. and any person responsibly connected with SereniGy Global, Inc.

USDA, AMS and SereniGy Global, Inc. have decided to compromise and settle the issues among them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and regulations promulgated thereunder (7 C.F.R. §§ 205 et seq.). The violations are explained below.

- SereniGy Global, Inc. is in violation of 7 CFR §205.100(a), §205.102, and 205.300(a) for representing the following uncertified products as certified organic.
  - o Gourmet Black Coffee
  - o Gourmet Latte
  - o Gourmet Mocha
  - Gourmet Hot Chocolate
  - o Gourmet Chai Tea
- SereniGy Global, Inc. is in violation of 7 CFR §205.100(a), §205.102, 205.300(a), and §205.311 for representing the following uncertified products as certified organic and using the USDA organic seal on uncertified products.
  - o Essential
  - o Time Capsule
  - o Slim
  - Fruit & Veggie Power Plus
- SereniGy Global, Inc. is in violation of 7 CFR §205.100 for use of a certificate falsely representing SereniGy Global, Inc. as a certified organic producer or handler.

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to file a formal administrative complaint charging SereniGy Global, Inc. with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. SereniGy Global, Inc. agrees to the following:
  - A. SereniGy Global, Inc. has been given the opportunity for a hearing and waives such hearing and further procedure for the purpose of settling this proceeding and for such purposes only.
  - B. SereniGy Global, Inc. agrees that failure to comply with the settlement agreement shall automatically void paragraph 2 above, and that USDA, AMS may thereafter institute a formal administrative proceeding against Serenigy Global, Inc., and pursue any and all remedies available under the OFPA and the regulations.

Serenigy Global, Inc. Settlement Agreement Page 2

- C. SereniGy Global, Inc. agrees to immediately cease and desist representing its noncertified products as certified organic and representing its company as a certified producer or handler.
- D. SereniGy Global, Inc. agrees to pay a reduced penalty of violations violations outlined above in full settlement of this matter.

This agreement will become effective upon receipt of payment.

Date: \_\_\_\_\_

Kent Bartell, Ph.D. Sr. VP of Product Research and Development SereniGy Global, Inc.

Date: \_\_\_\_\_

Miles McEvoy Deputy Administrator, National Organic Program USDA, AMS



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

VIA EXPRESS MAIL

Dr. Kent Bartell SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: SereniGy Global, Inc., Complaint Case NOPC-005-11

Dear Dr. Bartell:

The U.S. Department of Agriculture (USDA), National Organic Program (NOP), Compliance & Enforcement (C&E) Division is responsible for enforcing the Organic Foods Production Act of 1990, as amended, and its implementing regulations, as codified, in Title 7 of the Code of Federal Regulations, Part 205, National Organic Program. All agricultural products sold, labeled, or represented as organic must comply with the NOP regulations.

The NOP completed its investigation of SereniGy Global, Inc.'s (SereniGy) responses to the complaint filed against your company on October 14, 2010. The NOP determined that various SereniGy products and the Serenigy/Atlas Bioscience "organic certificate" are in violation of the NOP regulations. The three violations and associated regulatory references are presented below.

- 1. Violation of 7 CFR parts 205. 100(a), §205.102, and 205.300(a): Use of the term "100% certified organic" or similar phrase implying certification on the front panel of the following five coffee and tea products, which are not certified organic.
  - a. Gourmet Black Coffee
  - b. Gourmet Latte
  - c. Gourmet Mocha
  - d. Gourmet Hot Chocolate
  - e. Gourmet Chai Tea
- 2. Violation of 7 CFR parts §205.311, 205.100(a), §205.102, and 205.300(a): Use of the USDA organic seal and the term "100% certified organic" or similar phrase implying certification on the labels of the following four supplement products, which are not certified organic.
  - a. Essential
  - b. Time Capsule
  - c. Slim
  - d. Fruit & Veggie Power Plus
- 3. Violation of 7 CFR §205.100: Use of a certificate representing SereniGy as a certified organic producer or handler, when SereniGy does not have organic certification as a producer or handler.

Dr. Bartell Re: NOPC-005-11 Page 2

SereniGy must immediately **cease and desist** violating the NOP regulations. Additionally, §205.100(c) of the NOP regulations states that any operation that knowingly sells or labels a product as organic, except in accordance with OFPA, shall be subject to a civil penalty of not more than \$11,000 per violation.

The USDA is willing to settle this matter informally by offering you the enclosed settlement agreement as an alternative to initiating an administrative proceeding. Such an administrative proceeding would begin with the filing of a complaint describing the above violations of the OFPA. The case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Please note that your cooperation and corrective actions in this matter were considered in calculating the reduced settlement amount offered by the USDA.

Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. If you agree to the terms contained therein, please sign the original and return it to the address noted below by February 9, 2012, along with a certified check or money order made payable to the "Treasurer of the United States." Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave. SW Room 2646-S, Mail Stop 0268 Washington, D.C. 20250-0268

If you have questions please contact Renee Mann, Compliance & Enforcement Division, at (202) 205-5213 or renee.mann@ams.usda.gov.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program

Enclosure: Settlement Agreement



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

### CASE CLOSURE MEMORANDUM

- TO: Jennifer Tucker Associate Deputy Administrator, Acting Division Director NOP Compliance and Enforcement Division
- FROM: Renee Mann Compliance Specialist NOP Compliance and Enforcement Division
- SUBJECT: NOPC-005-11 SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

CERTIFYING AGENTS INVOLVED: Quality Assurance International, Nevada Department of Agriculture

COMPLAINANT: (b)(6),(b)(7)(c),(b)(7)(d)

ALLEGED VIOLATION: SereniGy Global Inc., produces products that do not have either a manufacturer or a certification agency listed on the packaging. The packaging states "100% certified organic" in violation of the NOP regulations.

SUMMARY: SereniGy Global, Inc., (SereniGy), 12 products: four coffees, three teas, and five supplements. Nine of these 12 products are in violation of the NOP regulations. The four coffees and one of the teas claim to contain 100% certified organic ganoderma (this statement is present on the front panel of the packaging) but are not certified. Four of the supplements claim to contain 100% certified organic seal on the back panel of the labels.

Three of SereniGy's products are not in violation of the regulations. One of these products is a supplement that makes no claims regarding the USDA organic seal or organic certification. The other two products are teas that are properly certified as 100% organic; these are private label teas that are produced by a certified organic processor that is certified by the Nevada Department of Agriculture.

The SereniGy company representative, Dr. BARTELL, explained why many of his labels were in violation of the regulations. His company thought the statement "100% certified organic ganoderma" on the front panels of its coffees and teas was a legal and accurate term that did not require certification because the entire product was not claimed to be organic. Also, because SereniGy's supplements contain certified organic ganoderma and are privately labeled by a company that makes some certified organic products (although the SereniGy supplements are not actually certified organic), SereniGy used the USDA organic seal on the back panel of its supplements.

SereniGy stated in February, 2011 that would bring its products into compliance with the NOP regulations. However, a misleading and possibly fraudulent certificate was discovered on the Serenigy website in December, 2011. For more information, see the Report of Investigation.

ACTION REQUESTED: Approval is requested to close case. A cease and desist notice as well as a settlement agreement will be issued to Serenigy regarding its labels and fraudulent certificate. (b)(5)

APPROVED FOR CLOSURE BY:

Jennifer Tucker

Date



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

# Report of Investigation

# UNITED STATES DEPARTMENT OFAGRICULTURE NATIONAL ORGANIC PROGRAM COMPLIANCE & ENFORCEMENT DIVISION

Complaint Number:	NOPC-005-11 )(6),(b)(7)(c),(b)(7)(d)
Complainant Name & Address:	
Operator Name & Address:	SereniGy Global Inc.
operator runne & runness.	201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131
Accredited Certifying Agent Nam	e & Address:
	Nevada Department of Agriculture 405 S. 21st St.

Date of Complaint:

October 14, 2010

Sparks, NV 89431

Allegation:

SereniGy Global, Inc. produces products that claim to be organic, but the complainant could not confirm the company's organic certification. The complainant specifically mentioned that the Gourmet Black Coffee and Gourmet Latte products do not identify a manufacturer or a certification agency on the packaging.

**Relevant Regulations:** 

Code of Federal Regulations, Title 7 Part 205, National Organic Program -

- §205.100(a) What has to be certified
- §205.100(c)(1) *Civil Penalty*
- §205.102 Use of the term, "organic"
- §205.300(a) Use of the term, "organic"
- §205.311 USDA seal

Date of Investigation:	November 1, 2010 to December 8, 2011

Date of Report:

December 8, 2011

Compliance Specialist:

Renee Mann

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- V. CONCLUSION & RECOMMENDATION

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- 4. First written contact attempt
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- 7. Confirmation of certification by Nevada Department of Agriculture (NDA)
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- 11. Certificate  $-^{(b)(4)}$
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- 15. SereniGy statement: it buys all of its ganoderma from <sup>(b)(4)</sup>
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### REPORT OF INVESTIGATION

# I. INTRODUCTION

The Compliance & Enforcement (C&E) Division of the National Organic Program (NOP) is responsible for investigating complaints filed under the Organic Foods Production Act of 1990 (7 USC 6501 et seq.) and its related laws and regulations.

On October 14, 2010, C&E received a complaint via the NOPCompliance@ams.usda.gov email address. An investigation of the allegation was conducted by gathering information from the manufacturer, SereniGy Global, Inc (SereniGy); two certifiers, Nevada Department of Agriculture (NDA) and Quality Assurance International (QAI); and a lab, Atlas Bioscience Inc. (Atlas Bioscience).

# II. ALLEGATION

SereniGy Global, Inc. produces products that claim to be organic, but the complainant could not confirm the company's organic certification. The complainant specifically mentioned that the Gourmet Black Coffee and Gourmet Latte products do not identify a manufacturer or a certification agency on the packaging.

# III. METHODOLOGY

Renee MANN, a Compliance Specialist, was assigned to investigate the complaint. She began the investigation by attempting to gather documentation from SereniGy. MANN had difficulty finding contact information for SereniGy and sent two letters to the company's physical address with no response (exhibits 4 and 5). SereniGy is a multi-level marketing (MLM) company with numerous independent vendors of its products. MANN called several of SereniGy's vendors and through these contacts she obtained an email address to a SereniGy executive. MANN emailed several SereniGy executives (exhibit 6) and was ultimately contacted by a different executive: Dr. BARTELL. BARTELL was cooperative throughout the investigation.

MANN contacted the two certifiers associated with the company. Both the Nevada Department of Agriculture (NDA) and Quality Assurance International (QAI) were asked to clarify whether SereniGy's beverages and supplements were certified. Both certifiers cooperated with the investigation by providing current labels and other documentation regarding SereniGy's products and the certified organic ganoderma ingredient.

Finally, MANN contacted Atlas Bioscience regarding what appeared to be a fraudulent certificate.

# IV. FINDINGS OF FACT

Page 4 of 7

# **ORIGINAL FINDINGS OF FACT, March 7, 2011:**

The SereniGy website advertises various coffees, teas, and supplements with claims of "organic" and "100% certified organic". These claims are made on pictures of the product labels (exhibit 3) and in the language describing the products (exhibit 2). All of the products that claim some amount of organic content contain a certified organic ganoderma (mushroom) ingredient.

BARTELL confirmed that two of the SereniGy products, organic rooibos tea and organic green tea, are certified by NDA (exhibit 7). He also explained that SereniGy's other products (coffees, chai tea, and supplements) are not certified organic products, but that each product contains certified organic ganoderma.

MANN asked BARTELL to submit the current labels for the products that contain the term "organic" on their labels (exhibit 8). NDA confirmed that the rooibos and green teas were indeed certified 100% organic products produced under a private label agreement (exhibit 9) and that the products contained organic ganoderma that is certified by QAI (exhibit 9a). NDA provided the current labels for the products (exhibit 9b), which NDA approved on March 25, 2010, and the previous labels that NDA found to be in violation of the NOP regulations (exhibit 9c).

BARTELL submitting a written explanation of the organic ingredients in each SereniGy product, an explanation of which products are certified (exhibit 10), a proof of purchase for the certified organic ganoderma (exhibit 10a), and the current and proposed labels for the products (exhibit 10b). MANN contacted QAI to confirm that the ganoderma was certified by QAI and to determine whether the four supplement labels that contain the QAI logo (Essential, Time Capsule, Slim, and Fruit & Veggie Power Plus) are certified by QAI. QAI responded that these products are not certified organic (exhibit 12) and are produced at a different facility that (b)(4) Inc. claims is certified (exhibit 13). QAI also confirmed that the ganoderma, which is produced by (b)(4)

Following these interactions, MANN informed BARTELL that his suggested labels for several products were still in violation of the NOP regulations. Specifically, the coffees and tea that were not certified still contained the word "100% certified ganoderma" in place of "100% certified organic ganoderma" on the front packaging; the NOP found both wording choices to be misleading. She also informed him that the supplements could not use the QAI logo if they were not certified organic (exhibit 14). BARTELL confirmed that he was in the process of having three of the four supplements certified by QAI (exhibit 15) and he submitted revised labels (exhibit 17), which are in compliance with the NOP regulations. He noted that the revised supplement labels would be used when purchasing new labels from <sup>(D)(4)</sup> (exhibit 16). BARTELL did not mention when the other product labels would be revised for the coffees, tea, and one supplement, because he had asked for approval from the NOP before printing these labels.

Regarding the violations, BARTELL explained that his company's understanding of the regulation was that only certified products could use the USDA organic seal, which is why the rooibos and green teas use the USDA organic seal and the supplements that SereniGy purchases as private label products through a certified operation, <sup>(b)(4)</sup> use the USDA Page 5 of 7

organic seal as well. For the products that BARTELL fully admitted were not certified, SereniGy assumed that the products were acceptably labeled as "with 100% certified organic ganoderma" because the ganoderma used in the SereniGy products is certified as 100% organic by QAI. Therefore, SereniGy asserts that it made a truthful statement that the products contained a certified ingredient.

# **UPDATED Findings of Fact, December 8, 2011:**

As of March, 2011 SereniGy was in the process of having its supplements certified organic through QAI and planned to change its uncertified product labels to remove the "certified organic" statements (exhibit 10b).

When MANN reviewed the SereniGy website in December, 2011, she found the same noncompliant labels and claims on the company website. MANN also found a certificate issued by Atlas Bioscience that claimed "Organic Certification" in the name of SereniGy Global, Inc. The certificate stated that "Serenigy global products contain USDA 100% certified organic Ganoderma…" MANN contacted SereniGy and Atlas Bioscience about the certificate. Atlas Bioscience admitted to creating the certificate and SereniGy noted that it requested the certificate to be made, to allow SereniGy to prove that it purchases certified organic ganoderma without disclosing its source of the ganoderma (by having to display the actual certificate issued by QAI to D(4) the supplier of the ganoderma).

# V. CONCLUSION & RECOMMENDATION

The complainant's allegation contained two parts: 1) SereniGy represents its products [presumably all of its products] as organic [without their certification being evident], and 2) the Gourmet Black Coffee and Gourmet Latte lack manufacturer information and certifier information on the packaging.

Regarding the first part of the allegation, nine SereniGy products were found to be in violation of the NOP regulations for being represented as certified organic without certification. This is explained in more detail below. Regarding the second part of the allegation, the presence of a manufacturer's name and address on the packaging is not relevant to the NOP because the products are not certified. Also, the lack of certifier information on the packaging is appropriate because the products are not certified. Therefore, the second part of the allegation does not constitute a violation in itself.

Returning to the first part of the allegation, nine SereniGy products are in violation of the NOP regulations. SereniGy confirmed that these nine products do not carry certification. However, the presence of the word "organic" anywhere except in the ingredient statement of a non-certified product is a violation of the NOP regulations. The following five products, which are not certified organic, claim "100% certified organic ganoderma" on the front panel of the labels:

- 1. Gourmet Black Coffee
- 2. Gourmet Latte
- 3. Gourmet Mocha

Page 6 of 7

- 4. Gourmet Hot Chocolate
- 5. Gourmet Chai Tea

The following four products, which are not certified organic, claim "100% certified organic" or "with 100% certified organic ganoderma" on the front panel of the labels and use the USDA organic seal on the back panel of the labels:

- 1. Essential
- 2. Time Capsule
- 3. Slim
- 4. Fruit & Veggie Power Plus

Finally, the certificate that was found on the SereniGy website is misleading and appears to fraudulently represent the company, Serenigy, as being a certified organic producer or processor.

### Regulatory References:

Code of Federal Regulations, Title 7 Part 205, National Organic Program -

- §205.100(a) What has to be certified
- §205.100(c)(1) *Civil Penalty*
- §205.102 Use of the term, "organic"
- §205.300(a) Use of the term, "organic"
- §205.311 USDA seal

### **Recommendation**

SereniGy's nine uncertified products that claim "organic" or "certified" or some combination thereof or that carry the USDA organic seal are in violation of \$205.100(a), \$205.102, and \$205.300(a) because they are representing the final product as certified but are not certified. C&E recommends sending a settlement agreement with civil penalty and cease and desist requirements to SereniGy. The civil penalty should be in the amount of \$4,000 for each of the three different types of violations: representing coffees and tea as organic, representing supplements as organic with the USDA organic seal, and using a fraudulent certificate. In total, this is \$12,000 (3 x \$4,000). The cease and desist should explain the violations of the NOP regulation on each SereniGy label and warn that the company may be fined \$11,000 per future violation.

# Additional Notes

This company is an appropriate candidate for future surveillance of its labels to determine that it followed through with certification and changing its labels.



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1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

### Settlement Agreement

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and SereniGy Global, Inc. and any person responsibly connected with SereniGy Global, Inc.

USDA, AMS and SereniGy Global, Inc. have decided to compromise and settle the issues among them related to three violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and regulations promulgated thereunder (7 C.F.R. §§ 205 et seq.). The violations are explained below.

- 1. SereniGy Global, Inc. is in violation of 7 CFR §205.100(a), §205.102, and 205.300(a) for representing the following uncertified coffees and teas as certified organic.
  - Gourmet Black Coffee
  - Gourmet Latte
  - Gourmet Mocha
  - Gourmet Hot Chocolate
  - Gourmet Chai Tea
- SereniGy Global, Inc. is in violation of 7 CFR §205.311, §205.100(a), §205.102, 205.300(a), and for using the USDA organic seal and representing the following uncertified supplements as certified organic.
  - Essential
  - Time Capsule
  - Slim
  - Fruit & Veggie Power Plus
- 3. SereniGy Global, Inc. is in violation of 7 CFR §205.100 for use of a certificate falsely representing SereniGy Global, Inc. as a certified organic producer or handler.

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to file a formal administrative complaint charging SereniGy Global, Inc. with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. SereniGy Global, Inc. agrees to the following:
  - A. SereniGy Global, Inc. has been given the opportunity for a hearing and waives such hearing and further procedure for the purpose of settling this proceeding and for such purposes only.
  - B. SereniGy Global, Inc. agrees that failure to comply with the settlement agreement shall automatically void paragraph 2 above, and that USDA, AMS may thereafter institute a formal administrative proceeding against Serenigy Global, Inc., and pursue any and all remedies available under the OFPA and the regulations.

Serenigy Global, Inc. Settlement Agreement Page 2

- C. SereniGy Global, Inc. agrees to immediately cease and desist representing its noncertified products as certified organic and representing its company as a certified producer or handler.
- D. SereniGy Global, Inc. agrees to pay a reduced penalty of \$12,000 for the three violations outlined above) in full settlement of this matter.

This agreement will become effective upon receipt of payment.

Date: \_\_\_\_\_

Kent Bartell, Ph.D. Sr. VP of Product Research and Development SereniGy Global, Inc.

Date: \_\_\_\_\_

Miles McEvoy Deputy Administrator, National Organic Program USDA, AMS



Agricultural Marketing Service 1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

### VIA EXPRESS MAIL

# JAN 1 0 2012

Dr. Kent Bartell SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: SereniGy Global, Inc., Complaint Case NOPC-005-11

Dear Dr. Bartell:

The U.S. Department of Agriculture (USDA), National Organic Program (NOP), Compliance & Enforcement (C&E) Division is responsible for enforcing the Organic Foods Production Act of 1990, as amended, and its implementing regulations, as codified, in Title 7 of the Code of Federal Regulations, Part 205, National Organic Program. All agricultural products sold, labeled, or represented as organic must comply with the NOP regulations.

The NOP completed its investigation of SereniGy Global, Inc.'s (SereniGy) responses to the complaint filed against your company on October 14, 2010. The NOP determined that various SereniGy products and the Serenigy/Atlas Bioscience "organic certificate" are in violation of the NOP regulations. The three violations and associated regulatory references are presented below.

- 1. Violation of 7 CFR parts 205. 100(a), §205.102, and 205.300(a): Use of the term "100% certified organic" or similar phrase implying certification on the front panel of the following five coffee and tea products, which are not certified organic.
  - a. Gourmet Black Coffee
  - b. Gourmet Latte
  - c. Gourmet Mocha
  - d. Gourmet Hot Chocolate
  - e. Gourmet Chai Tea
- 2. Violation of 7 CFR parts §205.311, 205.100(a), §205.102, and 205.300(a): Use of the USDA organic seal and the term "100% certified organic" or similar phrase implying certification on the labels of the following four supplement products, which are not certified organic.
  - (a. Essential
  - b. Time Capsule
  - c. Slim
  - d. Fruit & Veggie Power Plus
- 3. Violation of 7 CFR §205.100: Use of a certificate representing SereniGy as a certified organic producer or handler, when SereniGy does not have organic certification as a producer or handler.

Dr. Bartell Re: NOPC-005-11 Page 2

SereniGy must immediately **cease and desist** violating the NOP regulations. Additionally, §205.100(c) of the NOP regulations states that any operation that knowingly sells or labels a product as organic, except in accordance with OFPA, shall be subject to a civil penalty of not more than \$11,000 per violation.

The USDA is willing to settle this matter informally by offering you the enclosed settlement agreement as an alternative to initiating an administrative proceeding. Such an administrative proceeding would begin with the filing of a complaint describing the above violations of the OFPA. The case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Please note that your cooperation and corrective actions in this matter were considered in calculating the reduced settlement amount offered by the USDA.

Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. If you agree to the terms contained therein, please sign the original and return it to the address noted below by February 9, 2012, along with a certified check or money order made payable to the "Treasurer of the United States." Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave. SW Room 2646-S, Mail Stop 0268 Washington, D.C. 20250-0268

If you have questions please contact Renee Mann, Compliance & Enforcement Division, at (202) 205-5213 or renee.mann@ams.usda.gov.

Sincerely Miles V. McEvov

Deputy Administrator National Organic Program

Enclosure: Settlement Agreement

	11 Jan 2012	Tracking Number:	(b)(4)
1 Address Informat	lion		
Ship To: SereniGy Dr. Bartell 121 S. 2nd St. JENKS OK 740373920 Felephone: 918-724-4974	Ship From: USDA AMS/NOP rmann@ams 1400 Independence Ave SW 2 2646 Washington DC 20250 Telephone:2027203252	Return Address: USDA AMS/NOP renee.mann@ams.usda.gov 1400 Independence Ave SW 2 2646 Washington DC 20250 Telephone:2027203252	
2 Package Informa	tion		
Weight	Dimensions / Packagir	ng Declared Value	Reference Numbers
. 0.1 lbs (Letter billable)	UPS Letter	0.00 USD	Senders Initials - RM Reference # 2 - NOPC-005-11
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SereniGy Gourmet Spiced Black Tea is a proprietary blend made with the worlds finest organic tea and organic spices blended to taste perfection. Rich in gourmet flavor we also use the famous SereniGy 100% Certified Organic Ganoderma herb, containing all the powerful nutrients for your cells that the world's number one herb has to offer.





Products

Science of Ganoderma

# Our Products

# Coffee, Teas & More

Back To Life Challenge

- <u>Gourmet Black Coffee</u>
  - Gourmet Latte
  - Gourmet Mocha
  - Hot Chocolate
  - Gourmet Green Tea
  - <u>Gourmet Rooibos Tea</u>
  - <u>Chai</u>
  - Gourmet G-Roast
- Spiced Black Tea
- Nutritional Supplements
  - Essential Ganoderma
  - Time Capsules
  - Slim Weight Control
  - Fruit & Veggie
  - Lightning
- Structured Water
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- Our Executive Team
- Testimonials

### Products

- Gourmet Latte
- Gourmet Chai
- Time Capsules
- Fruit & Veggie Power Plus Capsules

#### Videos

- <u>SereniGy Lifestyle Opportunity Video</u>
- SereniGy Products Video! Part 1
- <u>SereniGy Products Video! Part 2</u>
- <u>The SereniGy Kids Mission Video!</u>

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SereniGy Gourmet Spiced Black Tea is a proprietary blend made with the worlds finest organic tea and organic spices blended to taste perfection. Rich in gourmet flavor we also use the famous SereniGy 100% Certified Organic Ganoderma herb, containing all the powerful nutrients for your cells that the world's number one herb has to offer.





Products

Science of Ganoderma



SG News

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- Our Executive Team
- Testimonials

### Products

- Gourmet Latte
- Gourmet Chai
- Time Capsules
- Fruit & Veggie Power Plus Capsules

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- SereniGy Products Video! Part 2
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SereniGy Gourmet Chai Tea is a naturally caffeine-free beverage made with 100% Certified Organic Rooibos Tea, high quality creamer, natural sugar, and special spice combined with an exclusive and proprietary blend of our 100% Certified Organic Ganoderma. We use a premium Organic Rooibos Tea that is naturally harvested and grown in the high regions of South Africa. Known for its own high levels of natural antioxidants, adding our exclusive blend of Organic Ganoderma creates a powerful and synergistic antioxidant combination. SereniGy has created the world's best Gourmet Chai Tea that will make you feel like royalty each time you enjoy a cup. Simply add hot water to our ready to serve gourmet beverage and get ready to experience a smooth and creamy pleasure sensation that you'll never forget. You'll want to enjoy this caffeine-free pleasure treat daily.



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SereniGy Fruit & Veggie Power Plus packs the essential nutrients from 7 fruits and 22 vegetables, along with 100% Certified Organic Ganoderma, into a convenient capsule designed to help you fulfill your daily dietary needs. This scientific and proprietary blend of 100% natural ingredients infuses your body with easily absorbed vitamins, minerals, amino acids, fiber, chlorophyll, enzymes, phytonutrients, and alkaline minerals that help to neutralize acids in your blood and tissues. The significant increase in concentration of these whole food nutrients results in broad nutritional balancing support for your body.

The nutrients in SereniGy Fruit & Veggie Power Plus do not contain any preservatives, diluents, or artificial additives, and are of the highest quality and purity obtainable to supply your body exactly what it needs for optimum nutritional support. Our fruit and vegetable extracts have a unique combination and full spectrum of the value that only whole food nutrients can offer. Vitamins, minerals and antioxidants from whole food sources have proven better than supplementation with individual vitamins, minerals or antioxidants. This is because many of the necessary nutrient co-factors are missing in laboratory-produced supplements that are not derived from a fresh fruit or vegetable whole food source. Concentrated grass juice powders from Wheat Grass, Barley Grass, Oat Grass, and Alfalfa are also some of the most alkalizing and nutrient-dense foods on the planet. The molecular structure of chlorophyll, which is often called "The Blood" of plants, is the same as human blood with the exception of the center atom. Your body has the ability to convert the center atom of chlorophyll with iron to form and build the blood to deliver adequate oxygen throughout your body.

Notwithstanding the well-documented benefits, unfortunately, most people don't eat enough servings of fresh greens, fruits or other vegetables. Using SereniGy Fruit & Veggie Power Plus capsules on a daily basis can help diets lacking the necessary daily recommended intake of raw fruits and vegetables.

Supplement Highlights:

- · Nutrient-Rich Fruit and Vegetable Extracts Formula
- 100% Certified Organic Ganoderma
- Each bottle contains 120 Capsules 750 mg each

Suggested Use: 2 Capsules two times daily



Disclaimer: These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure or prevent any disease.

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SereniGy G-Roast is a World Class Coffee that captures the true delicious flavor of our gourmet Arabica bean with an exceptionally deep roast taste. The savory undertones will leave you feeling naturally energized as you experience the rich smooth taste and pleasing aroma. 100% Arabica coffee beans are known as the better-tasting, specialty gourmet coffee and the coffee of choice for the finest coffee shops and avid coffee drinkers around the world. The unique and proprietary blend of our organic ganoderma through advanced Nano-technology is a life changing experience you will never forget that is only achieved through SereniGy gourmet beverages.

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SereniGy G-Drops is a concentrated water product that when added to pure water in the ratio of one (1) drop per ounce of pure water creates a bio-active Intelligent Structured drinking water. It is designed to rejuvenate the endocrine system, support nutrient absorption, normalize intestinal elimination, and support the body's own healing ability by flooding the tissues with an active form of oxygen, trace minerals and the power of hundreds of organic ganoderma micro nutrients.

# SERENIGY G-DROPS TECHNOLOGY

SereniGy Bio-active Intelligent Water (G-Drops) has been developed using three advanced proprietary technologies, which has created the world's first Ganoderma Frequency Structured Water.

The first technology in SereniGy G-Drops is a "Structured Water". This same type of "intelligent" water makes up the majority of the cellular fluid found inside the cells of healthy tissue in the body. "Structured Water" is known for its hydrating effects and considered "Bio-Active".

The second technology in the SereniGy G-Drops is a concentrated form of water known as a "wetting agent." When mixed according to the directions with pure water this creates a drinking water that has a high solubility for the nutrients the body needs. So vitamins, minerals and other nutrients, which are combined with the "wetter" structured water, tend to go from the digestive tract and bloodstream into the tissues and cells very rapidly. SereniGy's G-Drops (Structured "Wetter" Water), carries out cellular waste from the body more effectively, increasing the efficiency of metabolic cellular detoxification.

The third technology in SereniGy G-Drops is an exclusive and proprietary process that infuses the frequency energy of SereniGy Organic Ganoderma into the structured G-Drops concentrated water. This frequency can have an energetic effect on the body different than simply taking ganoderma supplements, because the energy is actually carried into each cell through the hydration process as a vibration captured and retained by the structured water. In addition to the frequency of Organic Ganoderma, we have also added an extract of Organic Ganoderma that is odorless and tasteless.

# DETOXIFICATION

In holistic medicine it is known that detoxification is an essential component in helping the body reach maximum health. "Structured Wetter Water" has been shown to help the body detoxify by supporting a natural healing process, which can include increased bowel detoxification and endocrine activation. Other indications of the benefits of Bio-Active Structured Water has been shown to help support the body's activation and use of cellular oxygen which directly supports the strength of the immune system. When this Bio-Active water is used with cooking water and taken with food, it helps the food nutrients to be properly absorbed by the body and supports the body's natural healing process. Many have found and believe that the detoxification support for the body is increased by 12 times when consistently taking Bio-Active Structured Water. The 2OZ bottle of G-Drops will make 75 pint size bottles of Bio-available Structured Water

## SUMMARY

Through advanced technology and physics, combined with specific soluble nutrients, SereniGy has been able to "imprint" a set of Ganoderma frequency patterns into structured water which can have various health supporting benefits. The proprietary frequencies and technology that SereniGy has incorporated into our exclusive SereniGy G-Drops (Bio-active Structured Water) makes SereniGy G-Drops Water the best water for all to drink on a daily basis.



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SereniGy Gourmet Organic Green Tea can provide a variety of possible health benefits with pure enjoyment. Experience the deep taste and top quality of this 100% certified organic source of green tea together with a blend of 100% Certified Organic Ganoderma. SereniGy travels all the way to India to bring you the finest green tea on the planet. Your taste buds will appreciate the difference and love you after just one sip. Whether you like your green tea brewed hot for sipping, or as a thirst-quenching iced tea, the SereniGy flavor is sure to please.



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SereniGy Gourmet Black Coffee will bring your senses to life with the rich smooth flavor and full aroma of the most enjoyable tasting coffee you have ever experienced. This pre-brewed gourmet beverage provides the best coffee has to offer without sugar or any artificial additives. We use only premium whole Arabica beans from locales like Brazil, Colombia and Guatemala that are world-renowned for their superior coffees. Our carefully selected beans, harvested while still green, undergo a special small batch roasting process that leads to a coffee that even the most discerning connoisseur will appreciate. What makes this coffee stand above all the rest is the addition of our proprietary blend of 100% Certified Organic Ganoderma, the world-renowned "King of Herbs." With the balance and nutritional complexity provided by this special ingredient, SereniGy Gourmet Black Coffee becomes the healthier coffee alternative.



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Rhonda Sellsted SG ID#: 100095 (306) 775-1996 Email Me

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SereniGy Gourmet Mocha is a dessert in a cup coffee that brings heaven to your mouth, as this smooth blend of coffee, cream and cocoa dance with taste sensations. Our delicious gourmet black coffee provides the perfect foundation for this rich indulgence, with the "King of Herbs", 100% Certified Organic Ganoderma, an essential ingredient. As a part of this cup of bliss, it makes for a combination that is out of this world! Give yourself the luxury of experiencing a healthier "Liquid Dessert Coffee" like you've never tasted before.



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SG News



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SereniGy Gourmet Mocha is a dessert in a cup coffee that brings heaven to your mouth, as this smooth blend of coffee, cream and cocoa dance with taste sensations. Our delicious gourmet black coffee provides the perfect foundation for this rich indulgence, with the "King of Herbs", 100% Certified Organic Ganoderma, an essential ingredient. As a part of this cup of bliss, it makes for a combination that is out of this world! Give yourself the luxury of experiencing a healthier "Liquid Dessert Coffee" like you've never tasted before.



Vatch Product Video

Producte

Science of Ganoderma Back To Life Challenge **Our Products** 

- Coffee, Teas & More Gourmet Black Coffee

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#### Click To Enlarge

SereniGy Gourmet Hot Chocolate is a rich deep blend of the finest Central American cocoa, fine cream and natural sugar, perfect for relaxing or giving yourself a treat. The addition of our proprietary blend of 100% Certified Organic Ganoderma to this beverage has many healthy possibilities for both adults and children. Kids are especially fond of this beverage – in fact, it was their unanimous choice during our product formulation taste tests. Just open our convenient flavor-sealed pack, mix with hot water, and you have the perfect drink for the whole family at any time of the day or night. Or add to ice cold milk for a refreshing, tasty and healthy treat sure to satisfy the strongest of chocolate cravings.



Watch Product Video

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SereniGy Gourmet Hot Chocolate is a rich deep blend of the finest Central American cocoa, fine cream and natural sugar, perfect for relaxing or giving yourself a treat. The addition of our proprietary blend of 100% Certified Organic Ganoderma to this beverage has many healthy possibilities for both adults and children. Kids are especially fond of this beverage – in fact, it was their unanimous choice during our product formulation taste tests. Just open our convenient flavor-sealed pack, mix with hot water, and you have the perfect drink for the whole family at any time of the day or night. Or add to ice cold milk for a refreshing, tasty and healthy treat sure to satisfy the strongest of chocolate cravings.



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005-11 Serenigy

February 14, 2012

Screen Images from product videos.

# Black Coffee



From the Gourmet Latte Video:



# Gourmet Mocha:



# Hot Chocolate:



# Green Tea:



# Rooibos Tea:



# Chai Tea:



# Essential:

In the video, the speaker states: "And so the capsule line consists of five specific products. We have, number one, the Essential, which is the pure ganoderma formula, which is very powerful. And I recommend that as basic support to help restore balance within the body. And I've helped so many of my patients and it's been the most powerful thing I've been able to do in my practice – any one single thing that I've been able to do for my patients has been Serenigy 100% Certified Organic Ganoderma."



# Time Capsule:



# Slim:


Fruit & Vegetable:



## Lightning:



## G-drops:







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SereniGy proudly offers a fine assortment of gourmet coffees, teas and hot chocolate, as well as a line of nutraceutical supplements, all containing our proprietary blends of 100% Certified Organic Ganoderma. Ganoderma, mostly unknown in the Western world until relatively recently, has been in use for thousands of years in traditional Asian medicine, where it has been associated with health, wellness, energy, longevity and balance, earning it the title "King of Herbs." SereniGy has located and secured sources for the purest and most potent forms of this special ingredient for use in its products.

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#### **Gourmet Beverages**

SereniGy's gourmet coffees begin with the superior Arabica bean grown on specially selected plantations known for producing the highest quality coffee beans in the world. We then use a proprietary small batch roasting process that brings out the full flavor and aroma of the bean, leading to a pre-brewed cup of gourmet coffee sure to please the most discriminating palate. Enjoy our Gourmet Black Coffee, or indulge in our Gourmet Latte and Gourmet Mocha.

Our line of gourmet teas is equally special, as all of our teas are derived from 100% organic sources using only the finest quality of tealeaves. The leaves are carefully harvested and dried, and then flavor-sealed in our premium teabags until you are ready to enjoy. If tea is your drink of choice, you are sure to note the superior taste and fragrance in our Gourmet Organic Green Tea, Gourmet Organic Rooibos Tea and Gourmet Chai Tea.

As a special treat for the whole family, you're also sure to enjoy our Gourmet Hot Chocolate, made from the finest cacao, cream and natural sugar. Kids love it!

The SereniGy line of gourmet beverages offers the convenience of single serve packets, perfect for home use or taking wherever you may be going. But don't let the small packages fool you into thinking these are run-of-the-mill instant beverages. These special products undergo exacting proprietary processes designed to capture the full flavor and aroma spectrums of their exceptional underlying ingredients. We freshly seal these in until you are ready to enjoy. Simply add hot water and you can begin to immediately savor our superior beverages. At last, true coffee shop quality beverages can be made affordably and by anyone. The best part is that not only will you find great tastes and aromas, but healthier hot beverage alternatives.

#### Nutraceuticals

With the ever-increasing awareness and popularity of Ganoderma, SereniGy also offers a line of nutraceutical supplements containing this highly sought after nutrient in capsule and tablet forms. We combine our various proprietary blends of the "King of Herbs" with other carefully selected nutritional ingredients to form a complete line of supplements providing balance and support to major body systems. Try our Ganoderma Essential or Ganoderma Time Capsules for pure Ganoderma, or our Slim Tablets or Fruit & Veggie Power Plus for additional nutrient ingredients. Our Lightning product is a nutrient catalyst and accelerator formulated for use with all of our supplements. Our nutraceuticals line provides a complete daily dietary supplement solution.

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### February 14, 2012

Screen Images from product sales page.







#### Click To Enlarge

SereniGy Gourmet Organic Rooibos Tea is made with 100% Certified Organic Rooibos Tea combined with an exclusive and proprietary blend of 100% Certified Organic Ganoderma. Our Organic Rooibos Tea is a naturally harvested herb that is grown in the high regions of South Africa and is naturally caffeine-free. Organic Rooibos Tea is known for having some of the highest levels of natural antioxidants, and combining it with our blend of Ganoderma creates a powerful and synergistic combination of antioxidants your body will love. You'll want to experience the naturally smooth, sweet taste of our Gourmet Organic Rooibos Tea on a daily basis. Enjoy hot, or as a refreshing iced tea treat.



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New Retail Order : Products

# Please enter the quantity for products you wish to add to your order.



\$100.00 (USD)





- 1 Bottle of SG Slim Tablets
- 1 Bottle of SG Lightning Capsules
- 1 Box of SG Organic Green Tea

80CV



• Increase Focus

32 CV

 SG G-Band Purple (M)

 Image: Constraint of the state of th

\$59.00 (USD)





The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

\$59.00 (USD)

## Qty SG G-Band Purple (Xtra-Large)



The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

\$59.00 (USD)



- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

### \$59.00 (USD)

Qty SG G-Band Pink (M)



The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

\$59.00 (USD)

Qty SG G-Band Pink (L)



The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

### \$59.00 (USD)

Qty SG G-Band Pink (Xtra-Large)

The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:





Qty SG G-Band Clear (M)

The SereniGy G-Band is the world's first



Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

\$59.00 (USD)

Qty

SG G-Band Clear (L)



The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

\$59.00 (USD)





The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

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https://backoffice.serenigy.com/orders/new\_retail\_order.php?sponsor\_username=101015&... 2/14/2012

32 CV

## \$59.00 (USD)



Qty SG Gourmet Black Coffee



SereniGy Gourmet Black Coffee will bring your senses to life with the rich smooth flavor and full aroma of the most enjoyable tasting coffee you have ever experienced. This pre-brewed gourmet beverage provides the best coffee has to offer without sugar or any artificial additives. We use only premium whole Arabica beans from locales like Brazil, Colombia and Guatamala that are world-renowned for their superior coffees. Our carefully selected beans, harvested while still green, undergo a special small batch roasting process that leads to a coffee that even the most discerning connoisseur will appreciate. What makes this coffee stand above all the rest is the addition of our proprietary blend of 100% Certified Organic Ganoderma, the worldrenowned "King of Herbs."

30 Sachets per Box

14 CV

\$27.00 (USD)



SG Gourmet Mocha Coffee

SereniGy Gourmet Mocha is a dessert in a cup



coffee that brings heaven to your mouth, as this smooth blend of coffee, cream and cocoa dance with taste sensations. Our delicious gourmet black coffee provides the perfect foundation for this rich indulgence, with the "King of Herbs", 100% Certified Organic Ganoderma, an essential ingredient. As a part of this cup of bliss, it makes for a combination that is out of this world! Give yourself the luxury of experiencing a healthier "Liquid Dessert Coffee" like you've never tasted before.

15 Sachets per Box

16 CV

\$29.00 (USD)

Qty

SG Gourmet Latte Coffee



SereniGy Gourmet Latte takes the joy of a cup of coffee to a place of ultimate fine taste. We begin with our superior gourmet black coffee and then bring to life the blended flavor of top quality creamer and natural sugar to produce a gourmet organic Ganoderma latte that you will never forget. The convenience of our pre-brewed packets makes this a healthier treat you can now experience on a daily basis.

20 Sachets per Box

14 CV

\$27.00 (USD)

## Qty SG Gourmet Hot Chocolate



SereniGy Gourmet Hot Chocolate is a rich deep blend of the finest Central American cocoa, fine cream and natural sugar, perfect for relaxing or giving yourself a treat. The addition of our proprietary blend of 100% Certified Organic Ganoderma to this beverage has many healthy possibilities for both adults and children. Kids are especially fond of this beverage – in fact, it was their unanimous choice during our product formulation taste tests. Just open our convenient flavor-sealed pack, mix with hot water, and you have the perfect drink for the whole family at any time of the day or night. Or add to ice cold milk for a refreshing, tasty and healthy treat sure to satisfy the strongest of chocolate cravings.

15 Sachets per Box

16 CV

\$29.00 (USD)

Qty SG Organic Green Tea



SereniGy Gourmet Organic Green Tea can provide a variety of possible health benefits with pure enjoyment. Experience the deep taste and top quality of this 100% certified organic source of green tea together with a blend of 100% Certified Organic Ganoderma. SereniGy travels all the way to India to bring you the finest green tea on the planet. Your taste buds will appreciate the difference and love you after just one sip. Whether you like your green tea brewed hot for sipping, or as a thirst-quenching iced tea, the SereniGy flavor is sure to please.

25 Sachets Per Box

17 CV

\$33.00 (USD)





SereniGy Gourmet Organic Rooibos Tea is made with 100% Certified Organic Rooibos Tea combined with an exclusive and proprietary blend of 100% Certified Organic Ganoderma. Our Organic Rooibos Tea is a naturally harvested herb that is grown in the high regions of South Africa and is naturally caffeine-free. Organic Rooibos Tea is known for having some of the highest levels of natural antioxidants, and combining it with our blend of Ganoderma creates a powerful and synergistic combination of antioxidants your body will love. You'll want to experience the naturally smooth, sweet taste of our Gourmet Organic Rooibos Tea on a daily basis. Enjoy hot, or as a refreshing iced tea treat.

SereniGy Gourmet Chai Tea is a naturally

25 Sachets per Box

17 CV

\$33.00 (USD)

SG Gourmet Chai Tea Qty

Qty



Quirmer Chai Cea	caffeine-free beverage made with 100% Certified Organic Rooibos Tea, high quality creamer, natural sugar, and special spice combined with an exclusive and proprietary blend of our 100% Certified Organic Ganoderma. We use a premium Organic Rooibos Tea that is naturally harvested and grown in the high regions of South Africa. Known for its own high levels of natural antioxidants, adding our exclusive blend of Organic Ganoderma creates a powerful and synergistic antioxidant combination. SereniGy has created the world's best Gourmet Chai Tea that will make you feel like royalty each time you enjoy a cup. Simply add hot water to our ready to serve gourmet beverage and get ready to experience a smooth and creamy pleasure sensation that you'll never forget. You'll want to enjoy this caffeine-free pleasure treat daily.
	15 Sachets per Box
	18 CV
	\$35.00 (USD)
SG G-Roast	
	SereniGy G-Roast is a world class coffee that captures the true delicious flavor of our Gourmet Arabica Bean with an exceptionally deep roast taste. The savory undertones will leave you feeling naturally energized as you experience the

rich smooth taste and pleasing aroma.



10 Filter Packs/box

\$49.00 (USD)

SG Ganoderma Essential Qty



Ganoderma Essential provides a daily dose of pure 100% Certified Organic Ganoderma in convenient capsule form. This full spectrum proprietary blend contains the most potent parts of the whole herb. In addition, this formula uses not just one type of Ganoderma, but includes all of the most effective forms of 100% Certified Organic Ganoderma in the world. Ganoderma Essential is designed for daily use by the whole family to help support balance to the body.

Supplement Highlights:

- Source of Pure Ganoderma
- 100% Certified Organic Ganoderma (450) mq)
- Each bottle contains 60 Capsules 450 mg each
- Suggested Use: 1-2 Capsules twice daily

60 Capsules per Bottle

32 CV

\$59.00 (USD)

#### Qty SG Time Capsules

The Ganoderma Time Capsule is a unique formula that is based upon years of clinical research and scientific study. Its time you try the most advanced Anti-Aging Ganoderma formula in the world, the SereniGy Ganoderma Time Capsule!



Supplement Highlights:

- Anti-Aging Formula
- Source of Pure Ganoderma
- Myco-Polysaccharide Molecular Complexes
- 100% Certified Organic Ganoderma Complex Blend
- Nanotechnology
- Each bottle contains 60 Capsules 500 mg each
- Suggested Use: 1-2 Capsules two times daily

60 Capsules per Bottle

56 CV

\$99.00 (USD)





SG Slim is designed to maximize healthy fat loss when used in conjunction with a proper diet and exercise program. For those not looking to lose weight, but who would like to improve their energy, stamina, and peak performance, SG Slim is a wonderful addition to your lifestyle and will exceed your expectations. For restoring physical performance and proper cellular metabolism to the body, SG Slim is simply the world's best formula available anywhere to naturally allow you to be your best.

Supplement Highlights:

- Weight Control Formula
- Athletic Performance Enhancement
- 100% Certified Organic Ganoderma
- Each bottle contains 90 Time Release Tablets - 750 mg each
- Suggested use: 1 tablet three times daily

90 Tablets per Bottle

48 CV

### \$89.00 (USD)

## Qty SG Fruit and Veggie Power Plus



SG Fruit & Veggie Power Plus are formulated capsules with a scientific blend of fresh fruit, vegetables & green grass juice extracts, providing a significant increase in concentration of these whole food nutrients resulting in a broad nutritional balancing support for your body all with 100% Certified Ganoderma.

Supplement Highlights:

- Nutrient-Rich Fruit and Vegetable Extracts
   Formula
- 100% Certified Organic Ganoderma
- Each bottle contains 120 Capsules 750 mg each
- Suggested Use: 2 Capsules two times daily

180 Capsules per Bottle

40 CV

## \$74.00 (USD)

## Oty SG Lightning Capsules



SereniGy Global Lightning Capsules are a complement product designed to accelerate the action of the SG 100% Organic Ganoderma Blend nutrients into the cells of your body. These capsules help maximize the effectiveness of Ganoderma in your system.

Supplement Highlights:

- Nutrient Catalyst and Accelerator for all Supplement Products
- Each bottle contains 90 Capsules 550 mg each
- Suggested Use: 1 Capsule to be taken each time any other supplement is taken

Qty

Qty

Qty

90 Capsules per Bottle 32 CV \$59.00 (USD) SG G-Drops SereniGy G-Drops is a concentrated water product that when added to pure water in the ratio of one (1) drop per ounce of pure water creates a bio-active Intelligent Structured drinking water. It is designed to rejuvenate the endocrine system, support nutrient absorption, normalize intestinal elimination, and support the body's own healing ability by flooding the tissues with an active form of oxygen, trace minerals and the power of hundreds of organic ganoderma micro nutrients. 23 CV \$44.00 (USD) SG G-Band (Small) The SereniGy G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to: Increase Balance Increase Core Strength • Increase Flexibility Increase Energy • • Increase Alertness Increase Focus 32 CV \$59.00 (USD) Case of SG G-Drops

12 Bottles of SG G-Drops

264 CV

Qty

Qty



\$59.00 (USD)

Qty SG G-Band (Xtra-Large)





Qty SG G-Band White (M)

The SereniGy Pink Power G-Band is the world's



first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

\$59.00 (USD)

Qty SG G-Band White (L)



The SereniGy Pink Power G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

\$59.00 (USD)

Qty SG G-Band (WXtra-Large)



The SereniGy Pink Power G-Band is the world's first Performance Band with the frequency of organic Ganoderma and is designed to:

- Increase Balance
- Increase Core Strength
- Increase Flexibility
- Increase Energy
- Increase Alertness
- Increase Focus

32 CV

## \$59.00 (USD)









Qty SG Capsule Power Pack

	<ul> <li>1 Bottle Each:</li> <li>SG Ganoderma Essential Capsules</li> <li>SG Time Capsules</li> <li>SG Slim Tablets</li> <li>SG Fruit and Veggies Power Plus Capsules</li> <li>SG Lightning Capsules</li> </ul>
	\$375.00 (USD)
Qty SG Tea Combo Pack	
OSCIANCE RECEIVER	1 box each: • SG Organic Green Tea • SG Rooibos Tea 33 CV \$63.00 (USD)
Qty SG Thin Pack	
is the doc	<ol> <li>Bottle- SG Fruit and Veggie Power Plus Capsules</li> <li>Bottle- SG Slim Tablets</li> <li>Bottle- SG Essential Capsules</li> <li>Bottle- SG of Lightning Capsules</li> <li>Box- SG Organic Green Tea</li> </ol>
	160 CV

\$300.00 (USD)



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SereniGy Slim Weight Control Formula is the world's most advanced formula for balancing weight through cellular energy production with 100% Certified Organic Ganoderma. Through research and biological analysis, this product is truly unlike anything currently available. It is scientifically formulated to naturally overcome physiological and hormonal imbalances resulting in an energetic, balanced and slender you.

SG Slim contains exclusive herbal complexes, each aimed at supporting fat loss through separate mechanisms. These mechanisms are designed to support proper sugar handling, appetite balancing, cellular energy production, and a healthy metabolism. This powerful formula is designed to maximize healthy fat loss when used in conjunction with a proper diet and exercise program. For those not looking to lose weight, but who would like to improve their energy, stamina, and peak performance, SG Slim is a wonderful addition to your lifestyle and will exceed your expectations. For restoring physical performance and proper cellular metabolism to the body, SG Slim is simply the world's best formula available anywhere to naturally allow you to be your best.

### Supplement Highlights:

- · Weight Control Formula
- Athletic Performance Enhancement
- 100% Certified Organic Ganoderma
- · Each bottle contains 90 Time Release Tablets 750 mg each
- · Suggested Use: 1 Tablet three times daily



- The SereniGy Kids Mission Video!

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Ganoderma Essential provides a daily dose of pure 100% Certified Organic Ganoderma in convenient capsule form. This full spectrum proprietary blend contains the most potent parts of the whole herb. In addition, this formula uses not just one type of Ganoderma, but includes all of the most effective forms of 100% Certified Organic Ganoderma in the world. Ganoderma Essential is designed for daily use by the whole family to help support balance to the body.

Supplement Highlights:

- Source of Pure Ganoderma
- 100% Certified Organic Ganoderma (450 mg)
- Each bottle contains 60 Capsules 450 mg each
- Suggested Use: 1-2 Capsules twice daily



Natch Product Video



#### 110 011 414

Producte

Science of Ganoderma Back To Life Challenge **Our Products** 

- Coffee, Teas & More
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SereniGy Lightning (Nutrient Catalyst) is a complementary product designed to accelerate the action of our Ganoderma blends and other supplemental nutrients into the cells of your body.

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One of the major factors to consider when taking any high potency nutritional product is your body's ability to adequately absorb the full spectrum of nutrients available within the product into your blood stream. When the hundreds of nutrients available in our 100% Certified Organic Ganoderma products get into your digestive tract, they are not actually in your body's physiology until they pass through the wall of your digestive tract and into your blood stream. If these nutrients are not fully able to absorb into your blood stream, they will simply pass through your body and be eliminated.

Due to daily stress and the resulting imbalance with body systems, most people have a reduced ability to fully absorb or digest the food nutrients in their diet and supplements. Taking this fact into consideration, SereniGy has scientifically formulated the Lightning proprietary support blend, which ensures that you get the maximum absorption of all the valuable nutrients available in all of our capsule and tablet products.

Supplement Highlights:

- · Nutrient Catalyst and Accelerator for all Supplement Products
- · Each bottle contains 60 Capsules 800 mg each
- Suggested Use: 1 Capsule to be taken each time any other supplement is taken



Watch Product Video

Producte

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  - Gourmet Mocha
  - Hot Chocolate
  - Gourmet Green Tea
  - Gourmet Rooibos Tea
  - Chai
  - Gourmet G-Roast
  - Spiced Black Tea
- Nutritional Supplements
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- The SereniGy Kids Mission Video!



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One of the major factors to consider when taking any high potency nutritional product is your body's ability to adequately absorb the full spectrum of nutrients available within the product into your blood stream. When the hundreds of nutrients available in our 100% Certified Organic Ganoderma products get into your digestive tract, they are not actually in your body's physiology until they pass through the wall of your digestive tract and into your blood stream. If these nutrients are not fully able to absorb into your blood stream, they will simply pass through your body and be eliminated.

Due to daily stress and the resulting imbalance with body systems, most people have a reduced ability to fully absorb or digest the food nutrients in their diet and supplements. Taking this fact into consideration, SereniGy has scientifically formulated the Lightning proprietary support blend, which ensures that you get the maximum absorption of all the valuable nutrients available in all of our capsule and tablet products.

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Valen Product Video

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There are many reasons Ganoderma is known as the world's best anti-aging herb, having stood the test of time for over 4,000 years. It is currently used today to help restore balance to the body, with powerful concentrations of Ganoderma through advanced science making a difference in lives around the world. The aging process takes its toll on everyone, and our Ganoderma Time Capsule works to turn back the body's time clock.

Our Ganoderma Time Capsule formula is the most advanced, full spectrum and bio-available form of Ganoderma as a nutritional supplement known to man. We start with the 100% Certified Organic Ganoderma complete complex used in our Ganoderma Essential product, and we then add a proprietary blend of 100% Certified Organic myco-polysaccharide molecular complexes. These supportive and unique complexes provide the body with the entire full spectrum of physiological support available through Ganoderma. We then use a highly technical laboratory process involving Nanotechnology to ensure the particle size of each molecule is extremely small, which allows the nutrients to be absorbed easily within minutes after entering your body.

The Ganoderma Time Capsule is a unique formula that is based upon years of clinical research and scientific study. Its time you try the most advanced Anti-Aging Ganoderma formula in the world, the SereniGy Ganoderma Time Capsule!

Supplement Highlights:

- Anti-Aging Formula
- Source of Pure Ganoderma
- Myco-Polysaccharide Molecular Complexes
- 100% Certified Organic Ganoderma Complex Blend
- · Nanotechnology
- · Each bottle contains 60 Capsules 500 mg each
- Suggested Use: 1-2 Capsules two times daily



The SereniGy Kids Mission Video!

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Our Ganoderma Time Capsule formula is the most advanced, full spectrum and bio-available form of Ganoderma as a nutritional supplement known to man. We start with the 100% Certified Organic Ganoderma complete complex used in our Ganoderma Essential product, and we then add a proprietary blend of 100% Certified Organic myco-polysaccharide molecular complexes. These supportive and unique complexes provide the body with the entire full spectrum of physiological support available through Ganoderma. We then use a highly technical laboratory process involving Nanotechnology to ensure the particle size of each molecule is extremely small, which allows the nutrients to be absorbed easily within minutes after entering your body.

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Supplement Highlights:

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- Source of Pure Ganoderma
- Myco-Polysaccharide Molecular Complexes
- 100% Certified Organic Ganoderma Complex Blend
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SereniGy Gourmet Latte takes the joy of a cup of coffee to a place of ultimate fine taste. We begin with our superior gourmet black coffee and then bring to life the blended flavor of top quality creamer and natural sugar to produce a gourmet organic Ganoderma latte that you will never forget. The convenience of our pre-brewed packets makes this a healthier treat you can now experience on a daily basis.



Watch Product Video

Producte

Science of Ganoderma Back To Life Challenge Our Products

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  - Hot Chocolate

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    - <u>Slim Weight Control</u>
       <u>Fruit & Veggie</u>

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Science of Ganoderma Back To Life Challenge Our Products

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  - Hot Chocolate

- Gourmet Green Tea
- Gourmet Rooibos Tea Chai
- Gourmet G-Roast
- Spiced Black Tea
- Nutritional Supplements
  - Essential Ganoderma
  - Time Capsules
  - Slim Weight Co
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expectations.

#### **Organic Rooibos Tea**



Gourmet Chai Tea

SereniGy's Organic Rooibos Tea is a naturally harvested herb grown in the high regions of South Africa. This is a delicious naturally caffeine-free beverage with a lot to offer. Taste and health in a cup that you can only get from one source -SereniGy. Try your cup of Organic Rooibos Tea today!

Gourmet Chai Tea containing 100% Certified Organic Ganoderma. What this Gourmet Chai Tea by SereniGy boils down to is this - your Organic Rooibos Tea

with some cream and sweeteners mixed in. This means you achieve your

naturally caffeine-free beverage while kicking in some extra taste. SereniGy's Gourmet Chai Tea provides a rich and exotic taste that will surpass all - 25 Tea Bags -Only: \$33

Add to Cart

- 15 Sachets -Only: \$35 Add to Cart

Only: \$59

Add to Cart

#### Ganoderma Essential



A self descriptive product - Ganoderma Essential - is just that. The essential - 90 Capsules components of Ganoderma put into capsule form. This aids those not looking for a hot drink but wish to benefit from the excellent support of Ganoderma to the body's system, and for those who want that extra level of intake. Each capsule contains 300mg of the wonderful herb Organic Ganoderma. While this herb is found in all of SereniGy's excellent products, this is your concentrated solution right here.

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#### **Raven Trapp Billie Andrews** Katrina Walters Judith Stockdale **Gayle Vaughan** Thomas & LaTrice Lockhart Danielle Halvorson **Connie Harvey Mindi Birkenholz** zipporah mesesi Kristen & Greg Henry Carolee & Lester Mack Suzanna Brown delores edwards **Danita Thomas** Lord Xodus Dan Lombardo Margie Davis -Sta **Eudora Hairston Christopher Minters Cynthia Freeman** Martin Flores Belinda Skoog **Carlos Maldonado** Deborah Griffin Michael Padilla Jim Kondo Wences Navarro Joyce Simpson Lisa Alonzo **Brigit Thomas** Zack Green **Chom Piccione** Mary Thompson **Tonya Miller Eddie Kimble** Kenneth Siciliano Marilyn Ramirez Joseph Cavieres Kepha Nyariki **Rohan Thompson** Thea Garvey adlene momant Andrea Moore Matthew Bright Carl Haley ted kannady

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# **Qualified BRONZE ASSOCIATES**

**Bryant Turner** 

CARRISA L. NIX

Barron Nelson

Karen Butler

Ida Benjamin Leslie Parms III

Kendra L. Duff

**Dalmon Murphy** 

**Cheron Berastequi** Kevin Muhammad

ElDalbric C. Hayden

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Dawn Barrett

Thomas Seals

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regenia leonard

Fred Taylor

Mary Ann Dyck

**Michael Davis** 

**Elvin Knox** 

Maricella Carvajal

Anthony & Tamekia Carey

Fred & Faridah Kamanya

Maricela & Juan Contreras



# Settlement Agreement

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and SereniGy Global, Inc. and any person responsibly connected with SereniGy Global, Inc.

USDA, AMS and SereniGy Global, Inc. have decided to compromise and settle the issues among them related to three violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and regulations promulgated thereunder (7 C.F.R. §§ 205 et seq.). The violations are explained below.

SereniGy Global, Inc. is in violation of 7 CFR §205.100(a), §205.102, and 205.300(a) for representing the Slim supplement as certified organic.

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to file a formal administrative complaint charging SereniGy Global, Inc. with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. SereniGy Global, Inc. agrees to the following:
  - A. SereniGy Global, Inc. has been given the opportunity for a hearing and waives such hearing and further procedure for the purpose of settling this proceeding and for such purposes only.
  - B. SereniGy Global, Inc. agrees that failure to comply with the settlement agreement shall automatically void paragraph 2 above, and that USDA, AMS may thereafter institute a formal administrative proceeding against Serenigy Global, Inc., and pursue any and all remedies available under the OFPA and the regulations.
  - C. SereniGy Global, Inc. agrees to immediately cease and desist representing its noncertified products as certified organic and representing its company as a certified producer or handler.
  - D. SereniGy Global, Inc. agrees to pay a reduced penalty of \$4,000 for the violation outlined above in full settlement of this matter.

This agreement will become effective upon receipt of payment.

Date: \_\_\_\_\_

Kent Bartell, Ph.D. Sr. VP of Product Research and Development SereniGy Global, Inc. Serenigy Global, Inc. Settlement Agreement Page 2

Date: \_\_\_\_\_

Miles McEvoy Deputy Administrator, National Organic Program USDA, AMS

\_\_\_\_



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

VIA EXPRESS MAIL

Dr. Kent Bartell SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: SereniGy Global, Inc., Complaint Case NOPC-005-11

Dear Dr. Bartell:

(b)(5)		 	

The USDA is willing to settle this matter informally by offering you the enclosed settlement agreement as an alternative to initiating an administrative proceeding. Such an administrative proceeding would begin with the filing of a complaint describing the above violations of the

Dr. Bartell Re: NOPC-005-11 Page 2

OFPA. The case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Please note that your cooperation and corrective actions in this matter were considered in calculating the reduced settlement amount offered by the USDA.

Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. If you agree to the terms contained therein, please sign the original and return it to the address noted below by March <u>1631</u>, 2012, along with a certified check or money order made payable to the "Treasurer of the United States." Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave. SW Room 2646-S, Mail Stop 0268 Washington, D.C. 20250-0268

If you have questions please contact Renee Mann, Compliance & Enforcement Division, at (202) 205-5213 or renee.mann@ams.usda.gov.

Sincerely,

Matthew Michael Director, Compliance & Enforcement Division National Organic Program

Enclosure: Settlement Agreement



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

VIA EXPRESS MAIL

Dr. Kent Bartell SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: SereniGy Global, Inc., Complaint Case NOPC-005-11

Dear Dr. Bartell:

Thank you for your letter dated February 6, 2012 regarding the National Organic Program (NOP) proposed civil penalty of \$12,000. I have reviewed the corrective actions identified by SereniGy Global, Inc. (SereniGy), which include revised product labels for nine SereniGy products and updates to the SereniGy website. The NOP originally determined that various SereniGy products and the SereniGy/Atlas Bioscience "organic certificate" were in violation of the NOP regulations. I acknowledge that SerniGy has updated its website and product labels in an attempt to bring its products and advertising materials into compliance with the NOP regulations in response to the NOP's compliance investigation.

Two SereniGy products remain in violation of the NOP regulations. Quality Assurance International (QAI) informed us that the Slim Supplement label has not been approved for individual sale and is therefore represented as certified organic in violation of the NOP regulations. Also, the Gourmet Chai Tea product contains the statement "100% certified rooibos" on the packaging, which implies organic certification in violation of the NOP regulations.

The NOP is willing to settle this matter by offering a revised civil penalty of \$4,000, instead of \$12,000. This reduced civil penalty is offered due to SereniGy's attempts to come into compliance with the NOP regulations and its continued violation of the NOP regulations at 7 CFR parts 205.100(a), \$205.102, and \$205.300(a) by representing the Slim supplement as certified organic.

The USDA is willing to settle this matter informally by offering you the enclosed settlement agreement as an alternative to initiating an administrative proceeding. Such an administrative proceeding would begin with the filing of a complaint describing the above violations of the OFPA. The case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Please note that your cooperation and corrective actions in this matter were considered in calculating the reduced settlement amount offered by the USDA.

Please read the enclosed settlement agreement that contains the terms under which the USDA is

Dr. Bartell Re: NOPC-005-11 Page 2

willing to settle this matter. If you agree to the terms contained therein, please sign the original and return it to the address noted below by March 16, 2012, along with a certified check or money order made payable to the "Treasurer of the United States." Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave. SW Room 2646-S, Mail Stop 0268 Washington, D.C. 20250-0268

If you have questions please contact Renee Mann, Compliance & Enforcement Division, at (202) 205-5213 or renee.mann@ams.usda.gov.

Sincerely,

Matthew Michael Director, Compliance & Enforcement Division National Organic Program

Enclosure: Settlement Agreement



1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

# Settlement Agreement

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and SereniGy Global, Inc. and any person responsibly connected with SereniGy Global, Inc.

USDA, AMS and SereniGy Global, Inc. have decided to compromise and settle the issues among them related to three violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and regulations promulgated thereunder (7 C.F.R. §§ 205 et seq.). The violations are explained below.

SereniGy Global, Inc. is in violation of 7 CFR §205.100(a), §205.102, and 205.300(a) for representing nine of its products as certified organic and for use of a certificate representing SereniGy as a certified organic producer or handler, when SereniGy does not have organic certification as an organic producer or handler.

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to file a formal administrative complaint charging SereniGy Global, Inc. with alleged violations of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. SereniGy Global, Inc. agrees to the following:
  - A. SereniGy Global, Inc. has been given the opportunity for a hearing and waives such hearing and further procedure for the purpose of settling this proceeding and for such purposes only.
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  - C. SereniGy Global, Inc. agrees to immediately cease and desist representing its noncertified products as certified organic and representing its company as a certified producer or handler.
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Serenigy Global, Inc. Settlement Agreement Page 2

This agreement will become effective upon receipt of payment.

Date: \_\_\_\_\_

Kent Bartell, Ph.D. Sr. VP of Product Research and Development SereniGy Global, Inc.

Date: \_\_\_\_\_

Miles McEvoy Deputy Administrator, National Organic Program USDA, AMS



Agricultural Marketing Service 1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

VIA EXPRESS MAIL

MAR 1 5 2012

Dr. Kent Bartell SereniGy Global, Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: SereniGy Global, Inc., Complaint Case NOPC-005-11

Dear Dr. Bartell:

Thank you for your letter dated February 6, 2012, regarding the National Organic Program (NOP) proposed civil penalty of \$12,000. As you know, the NOP initially determined that various SereniGy products and the SereniGy/Atlas Bioscience "organic certificate" were in violation of the NOP regulations. We have reviewed the corrective actions identified by SereniGy Global, Inc. (SereniGy), which include revised product labels for nine SereniGy products and updates to the SereniGy website.

Note that two SereniGy product labels remain in violation of the NOP regulations. Quality Assurance International (QAI) informed us that the Slim Supplement label has not been approved for individual sale and is therefore represented as certified organic in violation of the NOP regulations. Also, the Gourmet Chai Tea product contains the statement "100% certified rooibos" on the packaging, which implies organic certification in violation of the NOP regulations.

The NOP offers SereniGy a reduced civil penalty of \$4,000. This reduction reflects SereniGy's attempts to come into compliance with the NOP regulations, but also takes into account SereniGy's previously cited and continuing violations of the NOP regulations at 7 CFR parts 205.100(a), §205.102, and §205.300(a).

The USDA is willing to settle this matter informally by offering you the enclosed settlement agreement as an alternative to initiating an administrative proceeding. Such an administrative proceeding would begin with the filing of a complaint describing the above violations of the OFPA. The case would be heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation. Please note that your cooperation and corrective actions in this matter were considered in calculating the reduced settlement amount offered by the USDA.

Please read the enclosed settlement agreement that contains the terms under which the USDA is willing to settle this matter. If you agree to the terms contained therein, please sign the original and return it to the address noted below by March 31, 2012, along with a certified check or

Dr. Bartell Re: NOPC-005-11 Page 2

money order made payable to the "Treasurer of the United States." Our address is:

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave. SW Room 2646-S, Mail Stop 0268 Washington, D.C. 20250-0268

If you have questions please contact Renee Mann, Compliance & Enforcement Division, at (202) 205-5213 or renee.mann@ams.usda.gov.

Sincerely,

MAS

Matthew Michael Director, Compliance & Enforcement Division National Organic Program

Enclosure: Settlement Agreement

NOP Compliance and Enforcement Division Summary of Complaint Case SereniGy Global, Inc. NOPC-005-11

	(b)(5)(1),(b)(5)(2)		

(b)(5)(1),(b)(5)(2)		

Julia D. Allen ALLEN LAW OFFICE 3400 East 33<sup>rd</sup> Street Tulsa, Oklahoma 74135 (918) 585-5500 (918) 392-0510 facsimile juliadallen@vahoo.com

April 5, 2012

SENT VIA U.S. Mail, Certified, and email renee.man@ams.usda.gov Matthew Michael Director, Compliance & Enforcement Division National Organic Program 1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

Re: SereniGy Global, Inc. Complaint Case No. NOPC-005-11

Dear Mr. Michael:

This firm has been retained by the above with respect to their products and compliance with the National Organic Program Rules and Regulations. We are in receipt of your correspondence wherein the USDA offers to settle the alleged violations for the sum of \$4000.00 for civil penalties. We appreciate the Compliance & Enforcement Division's willingness to discuss the matters informally and your courteous cooperation with SereniGy Global.

My client is willing to perform the necessary steps to comply with the Agricultural Title and the specific regulations of the National Organic Program. Accordingly, this letter is a good faith effort to conform their products and operations to those specific provisions of the Code of Federal Regulations. In the March 15th letter, the USDA's explanation provided for the alleged violation is summed up in one paragraph that provides,

"[T]wo SereniGy product labels remain in violation of the NOP regulations. Quality Assurance International (QAI) informed us that the Slim Supplement label has not been approved for individual sale and is therefore represented as certified organic in violation of the NOP regulations. Also, the Gourmet Chai Tea product contains the statement "100% certified rooibos" on the packaging which implies organic certification in violation of the NOP regulations."

As you know, § 205.662 et.seq. of NOP's regulations provides the procedure for notification to SereniGy of alleged noncompliance. Pursuant to § 205.662(a), the "notification shall provide: (1) A description of each noncompliance; (2) The facts upon which the notification of noncompliance is based; and (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible." Moreover, when "the noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution." See § 205.662(b).

In the instant case, SereniGy was informed by way of letter January 10, 2012 from the USDA that there were three (3) instances of noncompliance; and that the USDA would settle the matter for the sum of \$12,000. Unfortunately, there was no indication of when the noncompliance must be corrected but a request that my client waive all its administrative procedural review and pay \$12,000. Now, SereniGy has received the correspondence

dated March 15, 2012, where two (2) violations are mentioned – with neither a required date for compliance or a description of the facts upon which the noncompliance is based. Similarly, the USDA has requested my client pay \$4000 and likewise waive any and all review. Moreover, there have apparently been alleged violations of compliance regulations that have been resolved. However, there's been no notice of resolution as required by CFR Tit.7, § 205.662(b). In the interim, my client has been expending valuable time and resources in an effort to resolve all indications of noncompliance expediently.

A review of the correspondence reveals that USDA has taken the position that the Compliance & Enforcement Division's listing of SereniGy's compliance violations has not been exhaustive. As a result, SereniGy is left to speculate as to what alleged violations have been resolved, what alleged violations remain, and what steps must be taken to satisfy the C&E of compliance with the applicable regulations. The USDA's failures to follow the basic notice requirements belies the regulations' public policy considerations of due process and makes it difficult for SereniGy to make budgeting and management decisions with any certainty. Consequently, this letter is a request that USDA outline the specific steps that are required to resolve the remaining violations as outlined in your March 15 correspondence; and thus, avoid any associated civil penalties and further compliance concerns for the existing products and/or marketing of SereniGy's products. Please feel free to contact me should you have any questions or need further information. We look forward to the amicable resolution of all SereniGy's certification issues and the continued working relationship with the National Organic Program.



Cc: SereniGy Global, Inc.
(b)(4

(b)(4)

Dear Mr. Terrell,

I apologize for the email and for being in a rush, but I am working under a deadline and hope to get a quick answer. Please see the email below, which I sent to Mr. Morr. I understand from Mr. Morr's automatic reply that he is out of the office and I hope that you can help me.

Thank you, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Dear Mr. Morr:

I need a quick answer to a question involving (b) (4) . I am looking at labels for SereniGy Global, a company that appears to have private labeled products produced by (b) (4) . I was previously in contact with Maria DeVincenzo. At the time, it appeared that SereniGy's products were not certified, but they carried the USDA seal and the QAI seal. Now, the products do not carry the USDA seal but they do carry QAI's seal and state that they are all certified by QAI. Can you please confirm that the following products are now certified by QAI:

- 1. Slim Dietary Supplement (label claim is "made with organic ganoderma")
- 2. Time Capsule Herbal Supplement (label claim is "made with organic ganoderma")
- 3. Essential Herbal Supplement (label claim is "made with organic ganoderma")

All of the above products contain organic ganoderma and all three claim "made with organic ganoderma" on the front panel. The company listed on the product label is SereniGy Global, Inc., 201 South Biscayne Blvd., Suite #2800, Miami, FL 33131. Please let me know if you have any questions.

Dear Mr. Morr:

I need a quick answer to a question involving (b) (4) . I am looking at labels for SereniGy Global, a company that appears to have private labeled products produced by (b) (4) . I was previously in contact with Maria DeVincenzo. At the time, it appeared that SereniGy's products were not certified, but they carried the USDA seal and the QAI seal. Now, the products do not carry the USDA seal but they do carry QAI's seal and state that they are all certified by QAI. Can you please confirm that the following products are now certified by QAI:

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Kind Regards,

Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

Hi Maria,

I'm sorry about the various emails; that was probably confusing. At first, I thought one email would go through with all 4 attachments, and then maybe 2 at a time, and ultimately I had to send the 3.5MB attachment separately. So, ultimately, you should have four different labels for the following products:

- 1. Time
- 2. Essential
- 3. Slim
- 4. Fruit & Veggie Power Plus

Please let me know if you received all of these labels.

Thanks,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <u>http://bit.ly/NOPOrganicInsiderRegistration</u>

Greetings!

I am currently out of the office and will be returning on February 23. Please contact Joe Terrell if youy need immediate assistance (734-827-6837)(terrell@nsf.org).

Thank you, Craig

### Hello Renee,

OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also.

Thank you,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: <<u>drbartell@serenigy.com</u>> Date: Mon, January 03, 2011 2:21 pm To: "Mann,Renee" <<u>Renee.Mann@ams.usda.gov</u>>

Dear Renee,

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

**Lightning:** No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification.

**Gourmet Black Coffee**, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site.

Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

## SereniGy Product Manufacturers: (Confidential Information)

(b)(4)



Please confirm you have received this email.

Sincerely,

Dr. Kent Bartell VP Product R & D

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Thu, December 30, 2010 8:33 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell:

It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline.

You are not expected to accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>.

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Hello Renee,

Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable?

Sincerely,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.

Sincerely,

Renee Mann

From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11

## Dear Dr. Bartell,

It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code of Federal Regulations, 7 CFR §205, National Organic Program.

Specifically, the complaint alleges that the Gourmet Black Coffee and Gourmet Latte are not certified as organic. Additionally, I have identified several other products on your website that may have labeling violations, which we discussed.

Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create labels that are compliant with the regulations. Pay specific attention to §205.100 *What has to be certified*, §205.101 *Exemptions and exclusions from certification* and Subpart D-Labels, Labeling, and Market Information.

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?

<u>c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7</u> If the above link does not work, you can also navigate to the regulations through the NOP website's Resource Center:

http://www.ams.usda.gov/NOPResourceCenterRegulations

In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010:

Submit the current product labels, including information and display panels, for the following products:

Gourmet Black Coffee Gourmet Latte Gourmet Mocha Gourmet Hot Chocolate Gourmet Chai Tea Organic Green Tea Gourmet Organic Rooibos Tea SG Ganoderma Essential SG Time Capsule

SG Slim SereniGy Fruit & Veggie Power Plus.

Submit revised labels for the abovementioned products that are compliant with the NOP regulations. Revise the abovementioned labels on the website, and ensure that references to "organic" products or ingredients are in compliance with the NOP regulations.

Identify the manufacturer of the abovementioned products that processes and labels the finished product. Supmit the organic certificate of the ganoderma that is used in the SereniGy products.

Provide a proof of purchase of the ganoderma (by the manufacturer identified in number 3 above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4)(iii) records must be maintained by the exempt handling operation).

Confirm that the Nutraceutical *SG Lightning* does not claim "organic" on its label. You could meet this requirement by submitting the current product label.

If you have any questions, please feel free to contact me at (202) 205-5213 or <u>renee.mann@ams.usda.gov</u>. Also, please note that I will be on vacation from December 20<sup>th</sup> through December 25<sup>th</sup>. If I am unavailable, you may contact a

representative of the NOP through the main NOP phone line at (202)720-3252.

Sincerely,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <a href="http://bit.ly/NOPOrganicInsiderRegistration">http://bit.ly/NOPOrganicInsiderRegistration</a>

From:	Mann, Renee - AMS	
То:	drbartell@serenigy.com	
Subject:	Case Closure and via Settlement Agreement	
Date:	Tuesday, January 10, 2012 5:39:00 PM	
Attachments:	2012-01-10 Closure settlement.pdf	
	2012-01-05 Settlement Agreement.pdf	

Dear Dr. Bartell:

Thank you for your emails before the holidays explaining the attestation of organic status of the ganoderma on SereniGy's website. Attached please find two documents. One is a letter explaining the findings of the National Organic Program's (NOP) investigation of a complaint filed against SereniGy. The second is a settlement agreement that the NOP proposes in lieu of filing a formal administrative complaint against SereniGy.

SereniGy has two options in the case of this proposed settlement. SereniGy is free to not accept the settlement agreement. In that case, the case will move forward to an Adjudicative Law Judge of the USDA. SereniGy can also sign the agreement and send the civil penalty amount to the USDA as instructed. This second action would close the case against SereniGy and the National Organic Program would not pursue any further action against SereniGy based on the violations found last year.

To explain further, I should note that the complaint investigation is fairly straightforward. You and I discussed how the terms "certified," "100% organic," and similar phrases made your finished products seem as if they were being represented as certified organic. Thank you for working with me to explain SereniGy's purchase of organic ganoderma. Unfortunately, the organic program takes those claims very seriously, even if SereniGy did not mean to be in violation of the law. Also, the use of a document that looked like an organic certificate was taken very seriously. These main problem areas led the program to levy a civil penalty. I trust that the attached settlement agreement with a civil penalty of \$12,000 will be acceptable to SereniGy. We can issue \$11,000 per violation, which can be levied per product, per product sale, per label printed, or even per use of the term "organic." As you can see, the fines can get into the hundreds of thousands of dollars if you are fined \$11,000 for every product you sold with the word "organic!" However, I argued in SereniGy's favor, that it did not know what it had done was in error, and that it meant to only represent its certified organic ganoderma as organic. We also discussed how cooperative you were during the investigation, and how this was the first warning you would be receiving.

I hope we can close this out via settlement and get SereniGy on the road to always understanding the regulations and never having to hear from me again! I will call you tomorrow to confirm that you have received these documents and to answer any questions you may have.

Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213 Stay informed by joining the National Organic Program mailing list.



## Complaint Investigation Chronology Log

Case #: NOPC-005-11

Subject: Serenigy Global Inc.

Compliance Specialist: Renee Mann

Date	Activity
10/14/2010	Complaint Received to the NOP Compliance email inbox.
10/28/2010	Complaint assigned to Renee MANN.
11/1/2010	MANN reviewed the file. Numerous uses of the term "organic" were found on the company's website, in addition to what the complainant mentioned. MANN had difficulty finding contact information for the company because no phone number or email address is given on the website. After searching unsuccessfully for the phone number through the yellow pages online, Better Business Bureau, FTC, and the state of Florida, MANN finally began looking up individual employees of the company through the yellow pages.
	MANN called a (b)(6),(b)(7)(c),(b)(7)(d) She found (7)(d) information on the Yellow Pages online. She left a message on an answering machine; the machine did not identify the person/location that she called, instead, it was the automatic response with which answering machines are pre-programmed.
11/12/2010	MANN again called $\binom{(b)(6),(b)(7)(c),(b)(7)}{(d)}$ at the phone number above. The same pre- programmed answering machine was reached. She left the same message asking to call her back.
	MANN mailed an initial contact letter to SereniGy by FedEx with a signature required for delivery of the letter.
11/17/2010	MANN received confirmation from FedEx that the package mailed to SereniGy was delivered on 11/17/2010 and signed for by (b)(6) (b)(6) is not listed as an executive on the SereniGy website, so it is uncertain who this person is.
	MANN mailed a second contact letter to SereniGy by FedEx with a signature required for delivery of the letter.
	MANN received confirmation from FedEx that the package mailed to SereniGy was delivered on $12/03/2010$ and signed for by (b)(6) (b)(6) is not listed as one of the nine executives on the SereniGy website, so it is uncertain who this person is.
12/6/2010	<ul> <li>MANN searched the internet and called individuals who sold SereniGy products as vendors for the MLM company.</li> <li>MANN called (b)(6),(b)(7)(c),(b)(7)(d) was unsure of the</li> </ul>



	at SereniGy who stated that the company had not received MANN's two hard-copy letters. MANN stated that both letters were sent with confirmation of delivery. BARTELL stated that the office is not populated by SereniGy employees and that a receptionist takes the mail and forwards it to a SereniGy executive, who is probably behind on the mail because he had a minor stroke in the past month.
12/7/2010	MANN called Steve MARTY of the NDA (office: 775-353-3373, cell: (b)(6) NDA had SereniGy product labels for green tea and rooibos on file. The products are private labels of (b)(4) which is certified. He noted that some older labels were noncompliant, and NDA had gotten SereniGy to create compliant labels that were approved on March 25, 2010. MANN asked MARTY to send the old and new, approved labels to her. MANN emailed BARTELL, giving him the contact information for the people she contacted on 12/6/2010.
	MANN emailed BARTELL with a request to submit information. MANN emailed BARTELL again and corrected the deadline for submission. (b)(5)
12/9/2010	(b)(5)
12/13/2010	(b)(5)
12/23/2010	BARTELL emailed MANN regarding a question for what was required by 1/3/2011.
12/30/2010	MANN responded to BARTELL's email by email.
1/4/2011	BARTELL emailed MANN noting that he had sent 3 emails the previous day. MANN emailed BARTELL to inform him that she had not received the emails. BARTELL re-sent the emails and MANN confirmed that each had been received. BARTELL emailed MANN regarding two questions.
1/5/2011	MANN responded to BARTELL's email.
1/6/2011	MANN called DEVINCENZO at QAI to discuss the possibility that the Serenigy products are certified by QAI. DEVINCENZO could not find information in the database that (b)(4) private labeled the three products. MANN emailed DEVINCENZO four labels to review. All four contained the QAI logo and the USDA seal.
1/10/2011	MANN received a phone message from DEVINCENZO. MANN called DEVINCENZO and they spoke about the fact that none of the Serenigy products are approved by QAI. DEVINCENZO noted that QAI would be sending Serenigy a

	cease and desist letter regarding the use of the QAI logo.
1/11/2011	MANN called DEVINCENZO because she had not yet received an email from her. DEVINCENZO had sent the email but the NOP email was faulty and was not delivering messages to NOP staff.
1/13/2011	MANN emailed DEVINCENZO to ask her to re-send the email and investigate whether <sup>(b)(4)</sup> knew about the Serenigy labels. DEVINCENZO emailed MANN, attached were the <sup>(b)(4)</sup> labels. MANN emailed DEVINCENZO in response.
1/17/2011	DEVINCENZO emailed MANN several documents showing Serenigy's response to the cease and desist letter and <sup>(b)(4)</sup> response to the inquiry.
1/19/2011	MANN emailed DEVINCENZO a response to her 1/17/2011 email.
1/27/2011	MANN emailed BARTELL regarding more changes to the labels. MANN called BARTELL and left a message on his voicemail offering to clarify why the QAI logo cannot be used. MANN called DEVINCENZO to give her an update on the label situation. She noted that the contact at <sup>(b)(4)</sup> seemed very confused as well. She noted that they would be contacting <sup>(b)(4)</sup> again to clarify the situation. DEVINCENZO said that <sup>(b)(4)</sup> said that it had a co-packer, but it doesn't appear to have one according to QAI's files. The co-packer could be certified by another certifier, or not certified at all.
1/31/2011	BARTELL emailed questions to MANN.
2/1/2011	MANN responded to BARTELL's questions.
2/8/2011	BARTELL emailed MANN an update to his progress in getting the <sup>(b)(4)</sup> manufactured products certified.
2/10/2011	BARTELL called MANN and they spoke about the requirements on the product labels.
2/17/2011	(b)(4) submitted labels to QAI and copied MANN. BARTELL wrote to MANN to inform her of this.
2/18/2011	BARTELL emailed MANN revised labels. MANN wrote back to confirm receipt.
3/7/2011	MANN submitted the report of investigation, complaint closure memorandum, and closure letters for review.
3/15/2011	BRADLEY returned the file to MANN for further investigation.
12/7/2011	MANN reviewed the file and the Serenigy website. Discovered a certificate that looks like a fraudulent certificate on the Serenigy website. MANN contacted the lab and SereniGy by email to request a response to the fraudulent certificate issue. MANN received a response from both the lab and SereniGy.
12/9/2011	MANN submitted drafts of a report of investigation, cease/desist/settlement letter, and settlement agreement for Jenny TUCKER, the acting Division Director of C&E, to review.
12/12/2011	BARTELL emailed MANN asking if she had received the response. MANN emailed BARTELL and confirmed. BARTELL emailed back saying "thanks."
01/10/2012	MANN emailed the settlement agreement and letter to BARTELL.
	MANN called and left a message on BARTELL's voicemail regarding the

	settlement. MANN emailed BARTELL to confirm that she had left a message. And
	asked which address to send the documents to. BARTELL emailed back asking MANN to send the documents to Oklahoma. MANN asked for the exact address in Oklahoma via email. MANN received the address via email. MANN mailed the cease and desist letter and the civil penalty via UPS 2 day express mail.
01/13/2012	BARTELL and Suzy GUILLORY, the VP of Corporate Development, called MANN to talk about the case at hand. (GUILLORY's contact info: <u>sguillory@serenigy.com</u> 720-422-1032). They asked questions about the settlement. They asked if they could be given an extension. MANN talked to Jenny TUCKER, associate deputy administrator, about providing an extension. TUCKER said it was OK. MANN emailed Serenigy to extend the deadline to Feb. 29.
1/25/2012	GUILLORY and BARTELL called MANN and again asked questions about the settlement. They suggested that they wanted to rebut the settlement and would do so in writing.
1/27/2012	MANN followed up by providing additional information re: FOIA which the two had requested by phone.
2/6/2012	BARTELL wrote to MANN requesting removal of the \$12,000 fine.
2/8/2012	GUILLORY wrote to MANN.
2/14/2012	MANN reviewed the SereniGy website in detail and copied pages to the file. MANN sent an email to Matthew Michael, the new Division Director of C&E, and Jenny Tucker to discuss the issue.
2/15/2012	MANN emailed GUILLORY and BARTELL, requesting the current products, labels & boxes.
2/20/2012	BARTELL emailed MANN to inform her that the labels would be arriving the next day.
2/21/2012	The requested labels arrived via mail.
2/22/2012	MANN emailed several people at QAI asking for current certification information on the supplement products. ALLEN responded with information about the supplements.
2/23/2012	MANN received voicemail from ALLEN asking for a copy of the Slim label. MANN scanned the label and sent to ALLEN via email.
2/29/212	MANN reviewed website. Old pictures of noncompliant labels have now been removed from the product pages and the videos in the product pages.
3/2/2012	MANN and the Division Director of C&E, Matthew MICHAEL, met to discuss the case. MANN wrote a draft settlement letter and agreement based upon the conversation for review by MICHAEL and MCEVOY. Submitted to MICHAEL for review.
3/8/2012	ALLEN emailed MANN an update regarding the case.
3/9/2012	BARTELL inquired about status of NOP's response.
3/12/2012	MANN spoke with MICHAEL who was still reviewing the revised settlement letter & agreement. MANN emailed BARTELL to tell him that a formal response would be forthcoming. MANN wrote to ALLEN asking for additional information.

3/13/2012	MICHAEL sent MANN his revisions to the letters. MANN reviewed, accepted changes, reprinted. Awaiting review by MICHAEL and perhaps MCEVOY. ALLEN responded to MANN's 3/12/12 question. MANN wrote back to confirm receipt and request that the investigation results be shared with her. ALLEN gave MANN additional information. MANN emailed ALLEN a response.
3/14/2012	ALLEN asked MANN when the containers were received. MANN responded via email.
3/15/2012	MANN received the signed settlement letter back from MICHAEL/MILES. Scanned docs. Sent settlement letter and agreement via UPS and email to Dr. Bartell.
3/16/2012	ALLEN emailed MANN regarding information obtained about (b)(4)
3/20/2012	BARTELL contacted MANN regarding the civil penalty/settlement.
3/26/2012	BARTELL sent a response regarding the civil penalty/settlement.
3/27/2012	MANN reviewed the response and emailed the response to MICHAEL, requesting a meeting. MANN & MICHAEL met regarding the case.
3/28/2012	MICHAEL sent a response to Serenigy via email.
3/29/2012	BARTELL and GUILLORY called MANN to discuss MICHAEL's response. They stated that they felt that the problems were not due to their negligence, but rather the NOP's failure to tell them everything that was wrong with their labels. They also stated that SLIM was now certified. MANN noted that this did not matter – the SereniGy products should have been in compliance originally. MANN spoke to MICHAEL about the phone call. MICHAEL wrote back to BARTELL to confirm that the settlement was still being offered but that the agreement and check could be received in the following week (instead of the upcoming weekend).
4/5/2012	Lawyer contacts MANN/MICHAEL.
4/17/2012	MICHAEL drafts response to lawyer.
4/18/2012	MANN reviews response. MICHAEL sent the response to the lawyer.
7/13/2012	MICHAEL sent summary of Serenigy case to OGC again.
7/20/2012	MICHAEL forwarded to MANN the OGC agenda and copy of the summary that he sent to OGC.
8/30/31/12	Chip Kidd, attorney, contacted Mann and asked for complaint file. Indicated that he would set up meeting with Matthew Michael.
9/5/2012	Matthew Michael contacted Chip Kidd & Mann to set up meeting.

Hello Renee,

I just wanted to confirm with you, did you receive my reply yesterday (3 emails total) with the 25 attached documents. RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Thank you,

Dr. Bartell

SereniGy VP Product R & D

From:	Steve J. Marty	
To:	Mann, Renee	
Subject:	(b)(4) SereniGy OPP and labels 120710.zip	
Date:	Tuesday, December 07, 2010 2:56:49 PM	
Attachments:	(b)(4) SereniGy OPP and labels 120710.zip	

Hello,

The approved Organic Product Profiles and labels as well as the non-compliant original labels for the two SereniGy products being packed by (b)(4) have been attached...sorry about the large file size. Please let me know if additioanl information is required. Thanks!

From:	Postmaster@kcc-mail-edge1.fsc.usda.gov	
To:	Mann, Renee	
Subject:	Delivery Notification <jnoland@serenigy.com></jnoland@serenigy.com>	
Date:	Monday, December 06, 2010 2:32:47 PM	
Attachments:	<u>ATT617982.txt</u>	
	SereniGy Organic Certification.msg	

This is a delivery status notification, automatically generated by MTA ftc-ems-gtw-av2.agent.one.usda.gov on Mon, 06 Dec 2010 12:32:45 -0700

Regarding recipient(s) : jnoland@serenigy.com

Delivery status : Failed. Message could not be delivered to domain <serenigy.com> .{'jnoland@serenigy.com': (550,

'#5.1.0 Address rejected jnoland@serenigy.com')}

MTA Response :N/A

The original message headers are included as attachment.

Document(s):	Letter to Complainant, Settlement Settlement Agreement	
Date:	3/2/2012	
Author:	Renee Ma	nn
File Location: (b)(7)(e)		
Approv	ved	Further Editing Required
Division Director Ir	nitials:	Matthew Michael Initials and Date
Remarks:		
	ved	Further Editing Required
Deputy Administrat	tor Initials:	Miles McEvoy Initials and Date
Remarks:		

# Return to MATTHEW MICHAEL





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EVIDENT SEAL IS BROKEN. DO NOT USE IF TAMPER

NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ. NO UTILIZAR SI ES EVIDENTE QUE EL SELLO ESTA ROTO. This product is not intended to diagnose, treat, cure or prevent any disease. Ce produit n'est pas conçu pour diagnostiquer, traiter, guérir ou prévenir une maladie.

tratar, curar o prevenir ninguna enfermedad Este producto no pretende diagnosticar,

Exclusively formulated and distributed by: Exclusivamente formulado y distribuido por: Préparé et distribué exclusivement par:



SerentGy Global, Inc. 201 South Blecayne Bivd., Suite #2800 Maml, FI 33131 Certified Organic by QAI





Statement and an other statements of the statement of the	-	Apr. 2013
	Lot No.:	÷

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN. NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ.

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Este producto no pretende diagnosticar, tratar, curar o prevenir ninguna enfermedad

Exclusively formulated and distributed by: Préparé et distribué exclusivement par: Exclusivamente formulado y distribuido por:

SereniGy Global, Inc. 201 South Biscayne Blvd., Suite #2800 Miami, FI 33131

From:	TrackingUpdates@fedex.com	
То:	Mann, Renee	
Subject:	FedEx Shipment (b)(4)	Delivered
Date:	Wednesday, November 17, 201	0 10:05:31 AM

This tracking update has been requested by:

Name:	Renee Mann
E-mail:	renee.mann@ams.usda.gov

Our records indicate that the following shipment has been delivered:

Reference:	Serenigy, NOPC-005-11		
Ship (P/U) date:	Nov 15, 2010		
Delivery date:	Nov 17, 2010 9:59 AM		
Sign for by:	M.BENITEZ		
Delivery location:	MIAMI, FL		
Delivered to:	Receptionist/Front Desk		
Service type:	FedEx Express Saver		
Packaging type:	FedEx Envelope		
Number of pieces:	1		
Weight:	0.50 lb.		
Special handling/Services:	Direct Signature Required Deliver Weekday		

Tracking number:

(4)

Shipper Information	Recipient Information
Renee Mann	Mr. Jay Noland
1400 Independence Ave SW	SereniGy Global Inc.
Room 2646-S	201 S BISCAYNE BLVD STE 2800
Washington	MIAMI
DC	FL
US	US
20250	33131

Please do not respond to this message. This email was sent from an unattended mailbox. This report was generated at approximately 9:03 AM CST on 11/17/2010.

To learn more about FedEx Express, please visit our website at fedex.com.

All weights are estimated.

To track the latest status of your shipment, click on the tracking number above, or visit us at <u>fedex.com</u>.

This tracking update has been sent to you by FedEx on the behalf of the Requestor noted above. FedEx does not validate the authenticity of the requestor and does not validate, guarantee or warrant the authenticity of the request, the requestor's message, or the accuracy of this tracking update. For tracking results and fedex.com's terms of use, go to <u>fedex.com</u>.

Thank you for your business.

Renee,

I had to change the type of file to reduce the large size as this was 7.5M. The #14 I also saved as a GIF file format. These will both open in Microsoft "Paint" if necessary to view.

Thank you,

Dr.

Bartell	
Original Message Subject: RE: File 15 of 25 From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> > Date: Tue, January 04, 2011 2:56 pm To: < <u>drbartell@serenigy.com</u> >	
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From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 4:33 PM To: Mann, Renee Subject: File 15 of 25	
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Thanks,	
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Dr. Bartell,	

I received this email and its one attachment. You can send one attachment per email if you would like.

Thank you,

Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee

Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11]

Hello Renee,

OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also.

Thank you,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: <<u>drbartell@serenigy.com</u>> Date: Mon, January 03, 2011 2:21 pm To: "Mann,Renee" <<u>Renee.Mann@ams.usda.gov</u>>

Dear Renee,

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

Lightning: No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification.

Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site.

Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

### SereniGy Product Manufacturers: (Confidential Information)



Please confirm you have received this email.

Sincerely,

Dr. Kent Bartell VP Product R & D

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Thu, December 30, 2010 8:33 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell:

It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline. You are not expected to accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>.

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Hello Renee,

Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable?

Sincerely,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.

Sincerely,

Renee Mann

From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11

Dear Dr. Bartell,

It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code



----- Original Message ------Subject: RE: File 15 of 25 From: "Mann, Renee" < Renee.Mann@ams.usda.gov > Date: Tue, January 04, 2011 2:56 pm To: <<u>drbartell@serenigy.com</u>> Dr. Bartell, I only received files 6 and 15. Renee From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 4:33 PM To: Mann, Renee Subject: File 15 of 25 ----- Original Message ------Subject: RE: Files 8 & 9 of 25 From: "Mann, Renee" < Renee.Mann@ams.usda.gov > Date: Tue, January 04, 2011 2:11 pm To: <<u>drbartell@serenigy.com</u>> Dr. Bartell, It appears that I am missing the email with Files 6 & 7 and Files 14 & 15. Thank you, Renee From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:58 PM To: Mann, Renee Subject: Files 8 & 9 of 25 ----- Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < Renee.Mann@ams.usda.gov > Date: Tue, January 04, 2011 1:52 pm To: <drbartell@serenigy.com> Success! From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] OK, I will see if two will go through. Please let me know if you get these. Thanks, Dr. Bartell ----- Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < Renee.Mann@ams.usda.gov > Date: Tue, January 04, 2011 1:44 pm To: <drbartell@serenigy.com> Dr. Bartell. I received this email and its one attachment. You can send one attachment per email if you would like. Thank you, Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] Hello Renee, OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also. Thank you, Dr. Bartell ----- Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: <<u>drbartell@serenigy.com</u>> Date: Mon, January 03, 2011 2:21 pm To: "Mann,Renee" < Renee.Mann@ams.usda.gov> Dear Renee, We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products Lightning: No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product. Time & Essential: These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well. Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification. Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply. We request a 6 month time period to exhaust our current product inventory (06/30/2011)We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the SereniGy.com web site. Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails. SereniGy Product Manufacturers: (Confidential Information) Please confirm you have received this email. Sincerely, Dr. Kent Bartell

VP Product R & D --- Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u>> Date: Thu, December 30, 2010 8:33 am To: <drbartell@serenigy.com> Dear Dr. Bartell: It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline. You are not expected to accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>. Sincerely. Renee Mann From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 Hello Renee, Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable? Sincerely, Dr. Bartell ----- Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" < Renee.Mann@ams.usda.gov> Date: Wed, December 08, 2010 10:56 am To: < drbartell@serenigy.com> Dear Dr. Bartell, I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010. Sincerely, Renee Mann From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11 Dear Dr. Bartell, It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code of Federal Regulations, 7 CFR §205, National Organic Program. Specifically, the complaint alleges that the Gourmet Black Coffee

and Gourmet Latte are not certified as organic. Additionally, I have identified several other products on your website that may

	have labeling violations, which we discussed.
	Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical
	products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create
	labels that are compliant with the regulations. Pay specific
	attention to §205.100 <i>What has to be certified</i> , §205.101 <i>Exemptions and exclusions from certification</i> and Subpart
	D-Labels, Labeling, and Market Information. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?
	c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno
	If the above link does not work, you can also navigate to the regulations through the NOP website's Resource Center:
	http://www.ams.usda.gov/NOPResourceCenterRegulations In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010:
Su	bmit the current product labels, including information and display panels, for the following products:
	Gourmet Black Coffee Gourmet Latte
	Gourmet Mocha Gourmet Hot Chocolate
	Gourmet Chai Tea Organic Green Tea Gourmet Organic Rooibos Tea
	SG Ganoderma Essential SG Time Capsule
	SG Slim SereniGy Fruit & Veggie Power Plus.
	bmit revised labels for the abovementioned products that are compliant with the NOP regulations.
	vise the abovementioned labels on the website, and ensure that references to "organic" products or ingredients are in compliance with the NOP regulations. partify the manufacturer of the abovementioned products that processes and
	labels the finished product. bmit the organic certificate of the ganoderma that is used in the SereniGy
	products. pvide a proof of purchase of the ganoderma (by the manufacturer identified in
	number 3 above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4)(iii) records must be maintained by the exempt handling operation).
Co	For that the Nutraceutical <i>SG Lightning</i> does not claim "organic" on its label. You could meet this requirement by submitting the current product label.
	If you have any questions, please feel free to contact me at
	(202) 205-5213 or <u>renee.mann@ams.usda.gov</u> . Also, please note that I will be on vacation from December 20 <sup>th</sup> through
	December 25 <sup>th</sup> . If I am unavailable, you may contact a
	representative of the NOP through the main NOP phone line at (202)720-3252.
	Sincerely,
	Renee Mann
	Compliance Specialist USDA National Organic Program
	(202)205-5213 office (202)205-7808 fax
	Join the NOP mailing list at
	http://bit.ly/NOPOrganicInsiderRegistration

------ Original Message ------Subject: RE: Files 8 & 9 of 25 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 2:11 pm To: <<u>drbartell@serenigy.com</u>>

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It appears that I am missing the email with Files 6 & 7 and Files 14 & 15.

Thank you,

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Success!

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11]

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SereniGy Product Manufacturers: (Confidential Information)


005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>> Dear Dr. Bartell, I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010. Sincerely, Renee Mann From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11 Dear Dr. Bartell, It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code of Federal Regulations, 7 CFR §205, National Organic Program. Specifically, the complaint alleges that the Gourmet Black Coffee and Gourmet Latte are not certified as organic. Additionally, I have identified several other products on your website that may have labeling violations, which we discussed. Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create labels that are compliant with the regulations. Pay specific attention to §205.100 What has to be certified, §205.101 Exemptions and exclusions from certification and Subpart D-Labels, Labeling, and Market Information. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx? c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7 If the above link does not work, you can also navigate to the regulations through the NOP website's Resource Center: http://www.ams.usda.gov/NOPResourceCenterRegulations In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010: pmit the current product labels, including information and display panels, for the following products: Gourmet Black Coffee Gourmet Latte Gourmet Mocha Gourmet Hot Chocolate Gourmet Chai Tea

Organic Green Tea Gourmet Organic Rooibos Tea SG Ganoderma Essential SG Time Capsule SG Slim SereniGy Fruit & Veggie Power Plus. Supmit revised labels for the abovementioned products that are compliant with the NOP regulations. vise the abovementioned labels on the website, and ensure that references to Re "organic" products or ingredients are in compliance with the NOP regulations. Identify the manufacturer of the abovementioned products that processes and labels the finished product. pmit the organic certificate of the ganoderma that is used in the SereniGy Su products. vide a proof of purchase of the ganoderma (by the manufacturer identified in number 3 above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4)(iii) records must be maintained by the exempt handling operation). firm that the Nutraceutical SG Lightning does not claim "organic" on its label. You could meet this requirement by submitting the current product label. If you have any questions, please feel free to contact me at (202) 205-5213 or renee.mann@ams.usda.gov. Also, please note that I will be on vacation from December 20<sup>th</sup> through December 25<sup>th</sup>. If I am unavailable, you may contact a representative of the NOP through the main NOP phone line at (202)720-3252. Sincerely, Renee Mann **Compliance Specialist USDA National Organic Program** (202)205-5213 office

Join the NOP mailing list at http://bit.ly/NOPOrganicInsiderRegistration

(202)205-7808 fax

From:	drbartell@serenigy.com
To:	Mann, Renee
Subject:	Files 4 & 5 of 25
Date:	Tuesday, January 04, 2011 3:55:50 PM
Attachments:	<u>Serenigy Black Coffee Box - current.jpg</u> <u>Serenigy Certificate of Analysis Aloha Medicinals.jpg</u>

Success!

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] OK, I will see if two will go through. Please let me know if you get these. Thanks, Dr. Bartell ----- Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:44 pm To: <<u>drbartell@serenigy.com</u>> Dr. Bartell, I received this email and its one attachment. You can send one attachment per email if you would like. Thank you, Renee From: <a href="mailto:drbartell@serenigy.com">drbartell@serenigy.com</a> [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] Hello Renee, OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also. Thank you,

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From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

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To:	Mann, Renee
Subject:	Files 8 & 9 of 25
Date:	Tuesday, January 04, 2011 3:58:26 PM
Attachments:	<u>Serenigy Essential Label - current.jpg</u> <u>Serenigy Fruit Veggie Label - current.jpg</u>

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(b)(4)

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Date:	Tuesday, January 04, 2011 3:59:26 PM
Attachments:	Serenigy gourmet black 12-29-10 revjpg Serenigy gourmet cocoa 12-29-10 revjpg

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	identified several other products on your website that may have
	labeling violations, which we discussed.
	Thank you for confirming which products are organic and for
	providing me with the information about the certifier of the green tea
	and rooibos tea. From our discussion, I understand that the ganoderma
	is certified organic, but the coffee is not certified organic. Also, I
	understand that the nutraceutical products, coffee products, and the
	chai tea are not certified. Please review the NOP regulations below so
	that you may create labels that are compliant with the regulations. Pay
	specific attention to §205.100 What has to be certified, §205.101
	Exemptions and exclusions from certification and Subpart D-Labels,
	Labeling, and Market Information.
	http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?
	c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7
	If the above link does not work, you can also navigate to the
	regulations through the NOP website's Resource Center:
	http://www.ams.usda.gov/NOPResourceCenterRegulations
	In order to respond to the complaint, the NOP requests that you provide us the
	following information by January 1, 2010:
su	brit the current product labels, including information and display panels, for the following products:
	Gourmet Black Coffee
	Gourmet Latte
	Gourmet Mocha
	Gourmet Hot Chocolate
	Gourmet Chai Tea
	Organic Green Tea
	Gourmet Organic Rooibos Tea SG Ganoderma Essential
	SG Time Capsule
	SG Slim
	SereniGy Fruit & Veggie Power Plus.
Su	pmit revised labels for the abovementioned products that are compliant with the NOP
	regulations.
хe	vise the abovementioned labels on the website, and ensure that references to "organic"
[de	products or ingredients are in compliance with the NOP regulations. ntify the manufacturer of the abovementioned products that processes and labels the
	finished product.
Su	mit the organic certificate of the ganoderma that is used in the SereniGy products.
	vide a proof of purchase of the ganoderma (by the manufacturer identified in number 3
	above) showing the purchase of ganoderma from a certified operation (per
~	\$205.101(a)(4)(iii) records must be maintained by the exempt handling operation).
Co	nfirm that the Nutraceutical SG Lightning does not claim "organic" on its label. You
	could meet this requirement by submitting the current product label.
	If you have any questions, please feel free to contact me at (202) 205-
	5213 or <u>renee.mann@ams.usda.gov</u> . Also, please note that I will be
	on vacation from December 20 <sup>th</sup> through December 25 <sup>th</sup> . If I am
	unavailable, you may contact a representative of the NOP through the
	main NOP phone line at (202)720-3252.
	main NOP phone line at (202)720-3252.
	main NOP phone line at (202)720-3252. Sincerely,
	Sincerely,

From:	drbartell@serenigy.com
To:	Mann, Renee
Subject:	Files 12 & 13 of 25
Date:	Tuesday, January 04, 2011 3:59:44 PM
Attachments:	Serenigy gourmet latte 12-29-10 revjpg Serenigy gourmet mocha 12-29-10 revjpg

Success!

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] OK, I will see if two will go through. Please let me know if you get these. Thanks, Dr. Bartell ----- Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:44 pm To: <<u>drbartell@serenigy.com</u>> Dr. Bartell, I received this email and its one attachment. You can send one attachment per email if you would like. Thank you, Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11]

Hello Renee,

OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also.

Thank you,

Dr. Bartell

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

**Lightning:** No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification.

Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site. Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

## SereniGy Product Manufacturers: (Confidential Information)

o) (4)

Please confirm you have received this email.

Sincerely,

Dr. Kent Bartell VP Product R & D

From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> >
Date: Thu, December 30, 2010 8:33 am
To: < <u>drbartell@serenigy.com</u> >

It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline. You are not expected to accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>.

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Hello Renee,

Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable?

Sincerely,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.

Sincerely,

Renee Mann

From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11

	complaint about your company. The complaint alleges that your
	company advertises some of its products as organic without
	certification, which is a violation of the NOP regulations. The NOP
	implements the Organic Foods Production Act of 1990 that requires
	that all agricultural commodities sold, labeled or represented as
	organic be certified by a United States USDA accredited certifying
	agent and must comply with the Code of Federal Regulations, 7 CFR
	§205, National Organic Program.
	Specifically, the complaint alleges that the Gourmet Black Coffee and
	Gourmet Latte are not certified as organic. Additionally, I have
	identified several other products on your website that may have
	labeling violations, which we discussed.
	Thank you for confirming which products are organic and for
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	and rooibos tea. From our discussion, I understand that the ganoderma
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From:	drbartell@serenigy.com
To:	Mann, Renee
Subject:	Files 16 & 17 of 25
Date:	Tuesday, January 04, 2011 4:02:14 PM
Attachments:	Serenigy Latte Coffee Box - current.jpg Serenigy Lightning Label - current.jpg

Success!

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] OK, I will see if two will go through. Please let me know if you get these. Thanks, Dr. Bartell ------- Original Message -------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:44 pm To: < <u>drbartell@serenigy.com</u>> Dr. Bartell, I received this email and its one attachment. You can send one attachment per email if you would like. Thank you,

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http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?	
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If the above link does not work, you can also navigate to the	20010110-7
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From:	drbartell@serenigy.com
To:	Mann, Renee
Subject:	Files 18 & 19 of 25
Date:	Tuesday, January 04, 2011 4:03:12 PM
Attachments:	<u>Serenigy Mocha Coffee Box - current.jpg</u> <u>Serenigy Organic Green Tea Box - current.pdf</u>

Success!

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] OK, I will see if two will go through. Please let me know if you get these. Thanks, Dr. Bartell ----- Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:44 pm To: < drbartell@serenigy.com> Dr. Bartell, I received this email and its one attachment. You can send one attachment per email if you would like. Thank you, Renee From: <a href="mailto:drbartell@serenigy.com">drbartell@serenigy.com</a> [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] Hello Renee,

OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also.

Thank you,

Dr. Bartell

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

**Lightning:** No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification.

Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site. Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

SereniGy Product Manufacturers: (Confidential Information)

b) (4)

Please confirm you have received this email.

Sincerely,

Dr. Kent Bartell VP Product R & D

From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> >
Date: Thu, December 30, 2010 8:33 am
To: < <u>drbartell@serenigy.com</u> >

It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline. You are not expected to accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>.

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Hello Renee,

Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable?

Sincerely,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.

Sincerely,

Renee Mann

From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11

complaint about your company. The complaint alleges that your	
company advertises some of its products as organic without	
certification, which is a violation of the NOP regulations. The NOP	
implements the Organic Foods Production Act of 1990 that requires	
that all agricultural commodities sold, labeled or represented as	
organic be certified by a United States USDA accredited certifying	
agent and must comply with the Code of Federal Regulations, 7 CFR	
§205, National Organic Program.	
Specifically, the complaint alleges that the Gourmet Black Coffee and	
Gourmet Latte are not certified as organic. Additionally, I have	
identified several other products on your website that may have	
labeling violations, which we discussed.	
Thank you for confirming which products are organic and for	
providing me with the information about the certifier of the green tea	
and rooibos tea. From our discussion, I understand that the ganoderma	
is certified organic, but the coffee is not certified organic. Also, I	
understand that the nutraceutical products, coffee products, and the	
chai tea are not certified. Please review the NOP regulations below so	
that you may create labels that are compliant with the regulations. Pay	
specific attention to §205.100 What has to be certified, §205.101	
<i>Exemptions and exclusions from certification</i> and Subpart D-Labels,	
Labeling, and Market Information.	
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?	
$\underline{c} = ecfr \& sid = 0 f dd 0 b 10 cc 7 b 2591 f e 145 f 95 c 95 da 42 b \& rgn = div5 \& view = text \& node = 7:3.1.1.9.3$	2  widno-7
If the above link does not work, you can also navigate to the	20010110-7
regulations through the NOP website's Resource Center:	
http://www.ams.usda.gov/NOPResourceCenterRegulations	
In order to respond to the complaint, the NOP requests that you provide us the	
following information by January 1, 2010:	
submit the current product labels, including information and display papels, for the	
Submit the current product labels, including information and display panels, for the following products: Gourmet Black Coffee	
following products: Gourmet Black Coffee Gourmet Latte	
following products: Gourmet Black Coffee Gourmet Latte Gourmet Mocha	
following products: Gourmet Black Coffee Gourmet Latte Gourmet Mocha Gourmet Hot Chocolate	
following products: Gourmet Black Coffee Gourmet Latte Gourmet Mocha Gourmet Hot Chocolate Gourmet Chai Tea	
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From:	drbartell@serenigy.com
To:	Mann, Renee
Subject:	Files 20 & 21 of 25
Date:	Tuesday, January 04, 2011 4:04:18 PM
Attachments:	<u>Serenigy Organic Rooibos Tea Box - current.pdf</u> <u>Serenigy Slim Label - current.jpg</u>

Success!

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] OK, I will see if two will go through. Please let me know if you get these. Thanks, Dr. Bartell ------- Original Message -------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:44 pm To: <<u>drbartell@serenigy.com</u>> Dr. Bartell, I received this email and its one attachment. You can send one attachment per email if you would like. Thank you,

Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11]

Hello Renee,

OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also.

Thank you,

Dr. Bartell

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

**Lightning:** No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification.

Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site. Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

SereniGy Product Manufacturers: (Confidential Information)

o) (4)

Please confirm you have received this email.

Sincerely,

Dr. Kent Bartell VP Product R & D

From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> >
Date: Thu, December 30, 2010 8:33 am
To: < <u>drbartell@serenigy.com</u> >

It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline. You are not expected to accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>.

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Hello Renee,

Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable?

Sincerely,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.

Sincerely,

Renee Mann

From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11
	complaint about your company. The complaint alleges that your
	company advertises some of its products as organic without
	certification, which is a violation of the NOP regulations. The NOP
	implements the Organic Foods Production Act of 1990 that requires
	that all agricultural commodities sold, labeled or represented as
	organic be certified by a United States USDA accredited certifying
	agent and must comply with the Code of Federal Regulations, 7 CFR
	§205, National Organic Program.
	Specifically, the complaint alleges that the Gourmet Black Coffee and
	Gourmet Latte are not certified as organic. Additionally, I have
	identified several other products on your website that may have
	labeling violations, which we discussed.
	Thank you for confirming which products are organic and for
	providing me with the information about the certifier of the green tea
	and rooibos tea. From our discussion, I understand that the ganoderma
	is certified organic, but the coffee is not certified organic. Also, I
	understand that the nutraceutical products, coffee products, and the
	chai tea are not certified. Please review the NOP regulations below so
	that you may create labels that are compliant with the regulations. Pay
	specific attention to §205.100 What has to be certified, §205.101
	Exemptions and exclusions from certification and Subpart D-Labels,
	Labeling, and Market Information.
	http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?
	c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7
	If the above link does not work, you can also navigate to the
	regulations through the NOP website's Resource Center:
	http://www.ams.usda.gov/NOPResourceCenterRegulations
	In order to respond to the complaint, the NOP requests that you provide us the
	following information by January 1, 2010:
su	brit the current product labels, including information and display panels, for the following products:
	Gourmet Black Coffee
	Gourmet Latte
	Gourmet Mocha
	Gourmet Hot Chocolate
	Gourmet Chai Tea
	Organic Green Tea
	Gourmet Organic Rooibos Tea SG Ganoderma Essential
	SG Time Capsule
	SG Slim
	SereniGy Fruit & Veggie Power Plus.
Su	pmit revised labels for the abovementioned products that are compliant with the NOP
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Co	nfirm that the Nutraceutical SG Lightning does not claim "organic" on its label. You
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	main NOP phone line at (202)720-3252.
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	Sincerely,

Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at http://bit.ly/NOPOrganicInsiderRegistration

From:	drbartell@serenigy.com
To:	Mann, Renee
Subject:	Files 22 & 23 of 25
Date:	Tuesday, January 04, 2011 4:05:16 PM
Attachments:	<u>Serenigy Time Label - current.pdf</u> slim capsule bottle new 12-28-10.jpg

------ Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:52 pm To: <<u>drbartell@serenigy.com</u>>

Success!

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] OK, I will see if two will go through. Please let me know if you get these. Thanks, Dr. Bartell ----- Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:44 pm To: <<u>drbartell@serenigy.com</u>> Dr. Bartell, I received this email and its one attachment. You can send one attachment per email if you would like. Thank you, Renee From: <a href="mailto:drbartell@serenigy.com">drbartell@serenigy.com</a> [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] Hello Renee,

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Thank you,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: <<u>drbartell@serenigy.com</u>> Date: Mon, January 03, 2011 2:21 pm To: "Mann,Renee" <<u>Renee.Mann@ams.usda.gov</u>> Dear Renee,

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

**Lightning:** No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

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SereniGy Product Manufacturers: (Confidential Information)

o) (4)

Please confirm you have received this email.

Sincerely,

Dr. Kent Bartell VP Product R & D

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

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Date: Thu, December 30, 2010 8:33 am
To: < <u>drbartell@serenigy.com</u> >

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Renee Mann

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Dear Dr. Bartell, It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a

	complaint about your company. The complaint alleges that your
	company advertises some of its products as organic without
	certification, which is a violation of the NOP regulations. The NOP
	implements the Organic Foods Production Act of 1990 that requires
	that all agricultural commodities sold, labeled or represented as
	organic be certified by a United States USDA accredited certifying
	agent and must comply with the Code of Federal Regulations, 7 CFR
	§205, National Organic Program.
	Specifically, the complaint alleges that the Gourmet Black Coffee and
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From:	drbartell@serenigy.com
To:	Mann, Renee
Subject:	Files 24 & 25 of 25
Date:	Tuesday, January 04, 2011 4:06:21 PM
Attachments:	time capsule bottle new 12-28-10 OPTION (1).jpg time capsule bottle new 12-28-10 OPTION (2).jpg

------ Original Message ------Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Tue, January 04, 2011 1:52 pm To: <<u>drbartell@serenigy.com</u>>

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Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site. Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

#### SereniGy Product Manufacturers: (Confidential Information)

o) (4)

Please confirm you have received this email.

Sincerely,

Dr. Kent Bartell VP Product R & D

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> >
Date: Thu, December 30, 2010 8:33 am
To: < <u>drbartell@serenigy.com</u> >

Dear Dr. Bartell:

It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline. You are not expected to accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>.

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, December 23, 2010 9:28 PM To: Mann, Renee Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Hello Renee,

Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable?

Sincerely,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.

Sincerely,

Renee Mann

From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: drbartell@serenigy.com Subject: SereniGy, NOP Complaint Case Number NOPC-005-11

Dear Dr. Bartell, It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a

	complaint about your company. The complaint alleges that your
	company advertises some of its products as organic without
	certification, which is a violation of the NOP regulations. The NOP
	implements the Organic Foods Production Act of 1990 that requires
	that all agricultural commodities sold, labeled or represented as
	organic be certified by a United States USDA accredited certifying
	agent and must comply with the Code of Federal Regulations, 7 CFR
	§205, National Organic Program.
	Specifically, the complaint alleges that the Gourmet Black Coffee and
	Gourmet Latte are not certified as organic. Additionally, I have
	identified several other products on your website that may have
	labeling violations, which we discussed.
	Thank you for confirming which products are organic and for
	providing me with the information about the certifier of the green tea
	and rooibos tea. From our discussion, I understand that the ganoderma
	is certified organic, but the coffee is not certified organic. Also, I
	understand that the nutraceutical products, coffee products, and the
	chai tea are not certified. Please review the NOP regulations below so
	that you may create labels that are compliant with the regulations. Pay
	specific attention to §205.100 What has to be certified, §205.101
	Exemptions and exclusions from certification and Subpart D-Labels,
	Labeling, and Market Information.
	http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?
	c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7
	If the above link does not work, you can also navigate to the
	regulations through the NOP website's Resource Center:
	http://www.ams.usda.gov/NOPResourceCenterRegulations
	In order to respond to the complaint, the NOP requests that you provide us the
	following information by January 1, 2010:
su	brit the current product labels, including information and display panels, for the following products:
	Gourmet Black Coffee
	Gourmet Latte
	Gourmet Mocha
	Gourmet Hot Chocolate
	Gourmet Chai Tea
	Organic Green Tea
	Gourmet Organic Rooibos Tea SG Ganoderma Essential
	SG Time Capsule
	SG Slim
	SereniGy Fruit & Veggie Power Plus.
Su	pmit revised labels for the abovementioned products that are compliant with the NOP
	regulations.
хe	vise the abovementioned labels on the website, and ensure that references to "organic"
[de	products or ingredients are in compliance with the NOP regulations. ntify the manufacturer of the abovementioned products that processes and labels the
	finished product.
Su	mit the organic certificate of the ganoderma that is used in the SereniGy products.
	vide a proof of purchase of the ganoderma (by the manufacturer identified in number 3
	above) showing the purchase of ganoderma from a certified operation (per
~	\$205.101(a)(4)(iii) records must be maintained by the exempt handling operation).
Co	nfirm that the Nutraceutical SG Lightning does not claim "organic" on its label. You
	could meet this requirement by submitting the current product label.
	If you have any questions, please feel free to contact me at (202) 205-
	5213 or <u>renee.mann@ams.usda.gov</u> . Also, please note that I will be
	on vacation from December 20 <sup>th</sup> through December 25 <sup>th</sup> . If I am
	unavailable, you may contact a representative of the NOP through the
	main NOP phone line at (202)720-3252.
	main NOP phone line at (202)720-3252.
	main NOP phone line at (202)720-3252. Sincerely,
	Sincerely,

Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at http://bit.ly/NOPOrganicInsiderRegistration Dear Dr. Bartell:

The FOIA information that you requested on Wednesday's phone call is below. Please contact Ms. Emmer Scott if you have questions about the FOIA process.

http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do? template=TemplateN&navID=Home&topNav=Home&page=FOIA&description=Freedom%20of%20Information%20Act%20(FOIA)

USDA, Agricultural Marketing Service Valerie L. Emmer Scott FOIA/PA Officer Rm 3521-S Ag Stop 0202 1400 Independence Ave., SW Washington, DC 20250-0273 Tel. (202) 720-2498 Fax. (202) 690-3767 E-Mail – <u>AMS.FOIA@usda.gov</u>

Kind Regards,

Renee Mann Compliance Specialist USDA National Organic Program (202) 205-5213 Dear Dr Bartell:

The United States Department of Agriculture's (USDA) <u>National Organic Program</u> (NOP) has identified a fraudulent certificate on the SereniGy Global, Inc. website: <u>http://www.serenigy.com/en/product/product-overview</u>. The certificate appears to have been produced by Atlas Bioscience, Inc. This certificate represents SereniGy Global, Inc. as having achieved "organic certification." The certification of companies is granted by certification agencies that are accredited by the USDA NOP. It does not appear that Atlas Bioscience, Inc. is an accredited certification agency.

Please contact me within the next 24 hours with an explanation as to why this certificate exists on the SereniGy website. If I do not hear from you by 6p.m. Eastern Standard Time on December 8, 2011, the NOP will proceed with posting this fraudulent certificate on its website with a warning to consumers.

Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division <u>National Organic Program</u> (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

Dear Dr Dinesh Patel:

The United States Department of Agriculture's (USDA) <u>National Organic Program</u> (NOP) has identified a fraudulent certificate on the SereniGy Global, Inc. website: <u>http://www.serenigy.com/en/product/product-overview</u>. The certificate appears to have been produced by Atlas Bioscience, Inc. This certificate represents SereniGy Global, Inc. as having achieved "organic certification." The certification of companies is granted by certification agencies that are accredited by the USDA NOP. It does not appear that Atlas Bioscience, Inc. is an accredited certification agency.

Please contact me within the next 24 hours with any information that you may have about this certificate. If I do not hear from you by 6p.m. Eastern Standard Time on December 8, 2011, the NOP will post this fraudulent certificate on its website.

Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division <u>National Organic Program</u> (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

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de prendre ce produit ou tout autre produit supplément.

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This product its not intended to diagnose, their, entry or prevent any discose,

women should consult with their doctor before using this or any other supplement. SUGGESTED USE: 2 capsules three times daily with food or snack. Pregnant or nursing

RECOMMANDÉE: Deux capsules trois fois par jour avec de la nourniture Les femmes enceintes ou qui allaitent doivent consulter leur médecin avant

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Exclusively formulated and distributed by Propare et distribue exclusivement per Exclusivamente formulado y distribuido por

SereniGy Global, Inc. 201 South Biscayne Blvd., Suite# 2800 Miami, FI 33131 Banaderma **Dietary Supplement** Certified with 100%

180 Capsules ~ 600 mg ea.

## Serving Size 2 Capsules Serving Per Container 90 % Darly Valu 670 mg 335 mg 335 mg 0 mg Supplement Facts Carbohydrate Amount Per Serving

Proprietary Herbal, Fruit and Vegetable Blend 1200 mg \*\* Acerola Cherry (fruit) Fenugreek (sprout) Amaranth (sprout) Spirulina (whole) Chlorella (whole) Strawberry (fruit) Blackberry (fruit Quinoa (sprout) Raspberry (fruit Blueberry (fruit) Wheat (sprout Kamut (sprout) Kale (leaf) Apple (frui Kiwi thuit Daily Values Based on a 2000 Calorie Diet Organic Ganoderma Lucidum (whole) Broccoli Juice (stalk and floweret Barley Grass Juice (aerial part) Wheat Grass Juice (aerial part) Oat Grass Juice (aerial part Alfalfa Juice (aerial part) Brussels Sprout (bud Cauliflower (floweret Green Pepper (fruit) Beet Juice (tuber Broccoli (sprout) Asparagus (stalk Spinach (leaf

\*\* Daily Value Not Established

Autres ingrédients. Ceiltulose Ve<mark>stutés Naturelle Capsules</mark> Contient Du Blé. De L'Orge Et. De L'Avoine Other Ingredients: Natural Cellulose Vegetable Capsule: Contains Wheat, Barley and Oats

Contains 100% Natural Fruit & Vegetable Blen tient 100% De Fruits Naturels Et Un Mélange Veg Cont

Hi Renee:

The attachment contains the SereniGy material I sent to OGC.

Thank you for acting and have a good week.

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov

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From: Michael, Matthew - AMS
Sent: Friday, July 13, 2012 11:04 AM
To: Paul, Robert - OGC; Ricci, Carrie; PICHELMAN, HEATHER - OGC; KIDD, CHIP W. - OGC
Cc: McEvoy, Miles - AMS; Courtney, Cheri - AMS; Bailey, Melissa - AMS; Tucker, Jennifer - AMS
Subject: Monthly NOP/OGC meeting

Hello:

Attached is the agenda and attachments for our monthly meeting next week. Let me know if you have any questions.

Thanks.

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

From:	Mann, Renee - AMS
To:	<u>Tucker, Jennifer - AMS</u>
Cc:	Michael, Matthew - AMS
Subject:	FW: NOP Request for Review
Date:	Tuesday, February 14, 2012 2:46:00 PM
Attachments:	NOP Reply Letter.doc

Dear Jenny and Matthew,

Attached is a letter from <u>SereniGy</u>, which is a company that is the subject of a complaint I am handling. Serenigy requested that I forward this letter to you. **Please review the letter and** (b)(5)

Kind Regards, Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Monday, February 06, 2012 11:11 PM
To: Mann, Renee - AMS
Cc: Suzy Guillory
Subject: NOP Request for Review

Hello Renee,

Please see the attached letter with the request for a review of our case. Please confirm you have received my request.

Thank you so much for your help,

Dr. Bartell

cc Ms. Suzy Guillory

From:	(b)(4)
To:	"Choychangthong, Kristi"
Cc:	Mann, Renee; drbartell@serenigy.com
Subject:	FW: SereniGy Essential, Slim & Time labels revised 2/17/11
Date:	Thursday, February 17, 2011 5:54:28 PM
Attachments:	essential capsule bottle new 02-15-11.pdf
	slim capsule bottle 02-15-11.pdf
	time capsule bottle 02-15-11.pdf

Hi Kristi,

I am forwarding you the attached labels which Dr. Bartell has corrected and made compliant. Could you review them and make sure they look ok on QAI's end?

I will then send to our encapsulator/tableter so they can be approved through their organic certifier (Organic Certifiers) as well as have the products added to their OSP. Once that is finalized, I will forward you their OSP so the finished/bottled products can be added to ours.

Please note that Renee from USDA is copied on this email so she can see that we have started the certification process for label compliance for Dr. Bartell.

Thank you and if you have any questions, please let me know!



### Maria,

It seems that your email program has a 3MB limit. I'll try sending one file per email.

Renee

From: Mann, Renee Sent: Thursday, January 06, 2011 6:13 PM To: maria@qai-inc.com Subject: Serenigy Global product line - email 1 of 2

Hi Maria,

Thank you for your help looking at these labels. Please let me know if QAI has reviewed and approved these labels.

The company, Serenigy Global, has informed me that the Serenigy Time, Serenigy Slim, and Serenigy Essential are manufactured by (b)(4). Also, while looking through the file after speaking with you I noticed another label for Serenigy Fruit & Veggie that is manufactured by (b)(4). This label also carries the QAI logo and the USDA organic seal.

Thanks again,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <u>http://bit.ly/NOPOrganicInsiderRegistration</u>

From:	Mann, Renee	- AMS
To:	Michael, Matth	new - AMS
Subject:	FW: SereniGy	Response regarding the NOP Letter
Date:	Tuesday, Marc	ch 27, 2012 9:57:00 AM
Attachments:	(b)(4)	.pdf
	RE(b)(4)	SereniGy.msg

Dear Matthew,

I would like you to review and help me respond to the latest email from Serenigy (NOPC-005-11), which is below (b)(5)

VIIICII		

I will also send you an invitation to discuss this as a meeting later this afternoon.

Thank You, Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Monday, March 26, 2012 1:25 PM
To: Mann, Renee - AMS
Cc: Suzy Guillory; Morgan Tharpe
Subject: SereniGy Response regarding the NOP Letter

Hello Renee,

I have had the opportunity to speak with our CEO on this matter and research the two items that NOP has claimed that we were not compliant on regarding labeling of our products. These were the Slim QAI logo and the Chai Tea "100% Certified Rooibos" phrase. I would like to provide an explanation in hopes that consideration may be made to accept our compliance in this matter as we have worked diligently to comply with all of the USDA NOP requirements as given and have been advised that we should not be fined for non-compliance. Thank you for consideration in this matter...

I was under the belief that all the product labels and boxes that I sent to you were compliant including the Chai Tea and the Slim Tablets. I had send both of these labels to you in pdf form last year on 2/18/2011 for your review and had not received any notice back that any of these had non-compliant information on

them. After getting your letter last week I quickly contacted (b)(4) (b)(4) said last year in the fall they had been working with their tableter for about 3 months on finalizing an organic tablet excipient formula that would work to make the Slim tablets hard enough. (b)(4) who takes care of processing the purchase orders thought that since (b) had submitted Time and Ganoderma Essential labels for approval as well as the Slim label for proof that we were working to be compliant, that approval with QAI was across the board for all 3 of these labels. Also around the same time she said she had received QAI approval for the Slim Powder, which also added to the internal confusion at (b)(4).

At the same time that (b)(4) released the 'trial' run of Slim bottles to us (which was unknown to (b)(4), she was working with their tableter and their organic certifying agency to get their approval for the completed Slim tablet. They just finally got the QAI approval from QAI and so the labels are clear to use. We request that you confirm with QAI and also see the attached document that lists the Slim product towards the bottom along with the Essential and Time capsules to use the QAI logo and release us from the fine associated with this product.

Regarding the Chai Tea, please see your response to our beverages section that you sent me on January 27th, 2011...

------ Original Message ------Subject: Response regarding organic labeling From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Thu, January 27, 2011 12:12 pm To: <<u>drbartell@serenigv.com</u>>

Dear Dr. Bartell,

Thank you for submitting your response on January 3, 2011 to the NOP regarding your various product labels that identify organic ingredients.

In relation to the Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate and Gourmet Chai Tea, the term "100% Certified" on the principal display panel (front panel) appears to reference the organic certification of the ganoderma ingredient. This is a violation of 7 CFR §205.100 and §205.305(a) because the claim could mislead customers to think that the entire coffee or tea product is 100% certified. Only products that are certified may be identified or represented as organic on the principal display panel. Please revise these labels again to remove the term "certified" and submit proofs to the NOP for review.

Renee, as per your instructions below we removed the term '100% certified" from all of the "principal display panel (front panel) of the boxes. It was never indicated that this term could not be listed on non-principal panels of the box. Regarding the Chai Tea, the "100% certified Rooibos" is not listed on the principal display panel (front face), but in the paragraph on the top of the box. I sent you a copy of this same box in February 2011. Our Rooibos Tea powder ingredient in this product is in fact a USDA certified organic herb and so the phrase "100% certified Rooibos" is accurate and does not give an indication that the entire product is certified organic. We followed the NOP instructions exactly to be compliant on all of our products and believe we should not be fined and the SereniGy NOP case closed.

Thank you for your continued help and we await your reply,

Sincerely,

Dr. Kent Bartell

cc Ms. Suzy Guillory V. P. cc Mr. Morgan Tharpe V.P.

### Hi Renee,

Below is the response I received from Serenigy regarding the cease and desist letter I sent. He seems a little confused regarding being able to label his product organic and the use of the USDA seal. As he states that he is waiting for your approval.

I also contacted  $^{(b)(4)}$  to make sure that they were not packaging and labeling this product. I received the attached emails from  $^{(b)(4)}$ , they also seem a little confused about the certification process. We will be contacting them tomorrow to see who there copacker is and if the facility is certified.

Regards.

Maria DeVincenzo Quality Specialist Quality Assurance International 9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 USA (858) 200-9727 Phone (734) 827-6177 Fax www.gai-inc.com



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From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, January 13, 2011 3:01 PM To: DeVincenzo, Maria Subject: RE: Unauthorized use of QAI seal

Hello Maria,

Our company SereniGy Global Inc. is a brand new company as of last year and has just begun with these new products. Thank you for the information regarding the labeling of our four products listed (Time capsules, Essential capsules, Fruit & Veggie Capsules, and Slim tablets) which we included the QAI logo. We have learned there was a misunderstanding and lack of information in the process of our design and wording of these labels that we applied. The reason we used the QAI logo is that the raw ingredient supplier of the Organic Ganoderma herb used in each of these four SereniGy products (<sup>(b)(4)</sup>)

by you and we believed we had the liberty to therefore use the logo on our labels as we are using this QAI certified organic ingredient.

Last month we were contacted by Renee Mann a Compliance Specialist with the USDA National Organic Program letting us know that these labels were believed to not be in compliance with the USDA organic labeling regulations. Upon review of the regulations we have recognized the errors of the labeling and have since changed these labels to reflect and be in compliant with the NOP. These new labels are currently being reviewed for approval and we are waiting for their approval at this time.

We wish to clarify this use of the logo with you so that we may correct our labels and be in complete compliance with your certification regarding our products and their labeling. I request that once the revised labels are approved by NOP, that we send you the approved labels for your review and approval for using the QAI logo on these products. Our intention is to fully comply with your certification requirements of which we will possibly need some guidance and review. Thank you for your consideration in this matter and please let me know if this process to correct our product labels is acceptable

Sincerely,

Dr. Kent Bartell SereniGy Global Inc. VP product R & D. 918-724-4974

The information in this email is considered proprietary and confidential.

------ Original Message ------Subject: Unauthorized use of QAI seal From: "DeVincenzo, Maria" <<u>Maria@qai-inc.com</u>> Date: Tue, January 11, 2011 3:50 pm To: <<u>drbartell@serenigy.com</u>> Cc: "NOPACAAdverseActions" <<u>NOPACAAdverseActions@ams.usda.gov</u>>

Dr Bartell,

Please see the attached correspondence regarding the unauthorized use of the QAI seal.

Maria DeVincenzo Quality Specialist Quality Assurance International 9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 USA (858) 200-9727 Phone (734) 827-6177 Fax www.qai-inc.com

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From:	Dr. Dinesh Patel
To:	Mann, Renee - AMS
Subject:	FW: USDA Organic certification
Date:	Wednesday, December 07, 2011 6:04:09 PM

Perhaps this will aid in clarifying your recent enquiry

At the request of the client for who we conduct analytical work they wish to conceal the source of their raw materials - we are not certifying their product as being Organic - merely that we have documentation and batch records from their suppler that does indeed show the incorporation of Organic Ganoderma into their products.

I hope this clarifies our position

Sincerely

Dinesh Patel Atlas Bioscience

-----Original Message-----From: lab [mailto:lab@atlas-bioscience.com] Sent: Sunday, October 30, 2011 12:12 PM To: 'drbartell@serenigy.com' Subject: RE: USDA Organic certification



Unfortunately we are not organic certifiers - can you get to send a copy of their Organic certification, then I can use that as a justification to create a certificate for you from us - I am happy to do this if I can have a valid paper-trail

-----Original Message-----From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Sunday, October 30, 2011 7:35 AM To: lab@atlas-bioscience.com Subject: USDA Organic certification

Hello Dr. Patel,

Based upon the documentation you have and testing, you mentioned you would be able to create a laboratory analysis certification form that verifies our Serenigy global products contain the USDA 100% certified organic Ganoderma. We need this laboratory analysis so that we can market to our customers our USDA organic status with our products that does not reveal our source of the herb being <sup>(D)(4)</sup>

Thank you,

Dr. Bartell Sent from my U.S. Cellular BlackBerryR smartphone



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6 February, 2012

Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program

Dear Ms. Mann,

I want to thank you for taking the time to talk to myself and Ms. Suzy Guillory, our VP of Corporate Development on January 13th, 2012. Please allow this email to recap our conversation. During our conversation, we expressed our concern in receiving the recent fine in the amount of \$12,000. This news was quite shocking to us, being that SereniGy complied with all of the USDA'S instructions to ensure that all of our labels, websites, and packaging had been corrected instantly on all new products. This occurred within a 1 to 2 month timeframe, the first part of 2011. I would also like to mention that at that time you indicated on the telephone to me that it would be acceptable to the NOP, and the case would be closed if we indicated these corrections would take place within a 6 month timeframe.

As stated above, we immediately took action making the approved changes as approved by the NOP with our printers, our different manufactures and our IT website developers. We also went to the extent of retaining product until the new labels could be produced and based all of these corporate decisions to comply specifically, and with urgency with the instructions that had been given directly to us by you. We considered this important, and our first priority in making sure SereniGy was compliant with the USDA NOP guidelines and directions given.

In an email to me on February 1<sup>st</sup>, 2011, you stated "*If you can prove to the NOP that you are in the process of getting the products certified and you can submit labels that are compliant with the NOP regulations (as if your products were currently certified) then I may be able to close the case on my end."* Within seventeen days later all of the labels were re-designed and submitted to you in a timely fashion as you had requested for all 9 products that needed to be corrected. Confirming the receipt of these files in an email to me dated February 18<sup>th,</sup> 2011, you stated "Dear Dr. Bartell: Thank you for the submissions. I have received all six of the emails and the Email from <sup>(b)(4)</sup> yesterday. I will be in contact with you once I am able to review the labels." This was the last communication I received from you until the December 7<sup>th</sup>, 2011 email with the subject "Fraudulent Organic Certificate".

SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131 PHONE: 888-316-7737 FAX: 888-316-7764 www.SereniGy.com



Please recall that I previously sent an email on December 7, 2011, concerning the following, in direct response to your email on that day regarding our website...

As for the recent notification regarding the certificate as I had mentioned in my email reply, Atlas Bioscience laboratory has done testing on our products for nutrient content as well as other tests as per our request. As a part of this process, Atlas has also reviewed and confirmed the organic certification of the USDA certified ganoderma certificates of Analysis from (b)(4) through QAI as SereniGy's source of the ganoderma herb we use in all of our products that contain this herb confirming it is indeed a USDA certified organic source. That was the only intended purpose of this document which I requested Atlas provide the document with such a statement. The statement on the document is accurate and it was not intended to indicate that SereniGy as a company is certified by the USDA through Atlas as we are not the source of the Ganoderma.

Our goal is to provide our customers and distributors some validation that we use only a USDA certified organic source of Ganoderma which we do. However our source for the herb is proprietary and therefore we cannot post the (b)(4) QAI certification document and reveal our manufacturer.

I had the document taken down immediately (in less than an hour) from our website as soon as I received your email until I had clarification from you as to how we could correct this to provide a third party laboratory validation that our Ganoderma has been confirmed as a certified source without revealing our source of the herb and be acceptable to the NOP. I indicated that there must be some way to show the public validation we use a certified organic herbal source in our product without revealing our source. My questions in this email were never responded to and I did not hear back from you regarding this email.

It is our goal and mission at SereniGy to handle everything with Integrity. We have made prompt and conscientious efforts to comply with the NOP and establish an excellent working relationship. For the reasons above, we feel that our company has been treated unfairly. It even appears that our case fell through the cracks, given the time that went by without us receiving any notice that our case was closed or that we needed to supply any further information. At this time, SereniGy is humbly requesting that you submit our concerns and our response to your immediate Supervisor to review our case once again. In hopes, that the \$12,000 fine will be removed.

Kind Regards,

Dr. Kent Bartell Vice-President of Product Research and Development

> SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131 PHONE: 888-316-7737 FAX: 888-316-7764 www.SereniGy.com

From:	drbartell@serenigy.com
To:	Mann, Renee - AMS
Cc:	Suzy Guillory
Subject:	NOP Request for Review
Date:	Monday, February 06, 2012 11:11:12 PM
Attachments:	NOP Reply Letter.doc

Hello Renee,

Please see the attached letter with the request for a review of our case. Please confirm you have received my request.

Thank you so much for your help,

Dr. Bartell

cc Ms. Suzy Guillory

From:	Mann, Renee - AMS
To:	Bartell (drbartell@serenigy.com); "sguillory@serenigy.com"
Subject:	NOPC-005-11
Date:	Friday, January 13, 2012 4:38:00 PM

Dear Dr. Bartell and Ms. Guillory:

I am writing to inform you that the NOP is granting you an extension to respond to Mr. McEvoy's letter dated January 10, 2012. If you agree to the terms contained in the settlement agreement, please sign the original and return it to the address noted in Mr. McEvoy's letter by February 29, 2012, along with a certified check or money order made payable to the "Treasurer of the United States." Please note that if the NOP has not received both the signed settlement agreement and certified check or money order by February 29, 2012, the NOP will pursue a formal administrative proceeding against SereniGy Global, Inc.

Also, please note that the U.S. Postal Service delivery to the USDA building is inconsistent and it is best to send documents to the NOP via UPS or FedEx to meet your deadline.

Sincerely,

Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213
# NOP and OGC Meeting Agenda for July 19, 2012 9:30 – 11:00 am; Room 2646

(b)(5)(1),(b)(5)(2)		



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

# United States Department of Agriculture Agricultural Marketing Service National Organic Program, Compliance & Enforcement Division Washington, DC

Date of Report February 12, 2012 Case Number NOPC-005-11 Report Made By: Matthew Michael

Director, C&E Division Renee Mann Compliance Specialist

#### TITLE (VIOLATOR):

**SereniGy Global Inc.** 201 S. Biscayne Blvd., Ste 2800 Miami, FL 33131

#### VIOLATIONS:

Representation of coffee, tea, and supplements as organic without certification in violation of

- 1) Organic Foods Production Act of 1990, 7 USC 6505(a) COMPLIANCE REQUIREMENTS, DOMESTIC PRODUCTS, and
- 2) National Organic Program, 7 CFR, Title 7 Part 205 §205.100(a) What has to be certified.



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

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Date of Report February 12, 2012 Case Number NOPC-005-11 Report Made By: Matthew Michael Director, C&E Division

Renee Mann Compliance Specialist

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SereniGy Global Inc. 201 S. Biscayne Blvd., Ste 2800 Miami, FL 33131

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- 2) National Organic Program, 7 CFR, Title 7 Part 205 §205.100(a) What has to be certified.

### SYNOPSIS OF FACTS:



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

# United States Department of Agriculture Agricultural Marketing Service National Organic Program, Compliance & Enforcement Division Washington, DC

Date of ReportCase NumberDecember xx, 2012NOPC-005-11

Matthew Michael Director, C&E Division Renee Mann Compliance Specialist

Report Made By:

Hello Renee,

It was a pleasure and informative speaking with you this afternoon regarding our labels. Here is our certifier for our USDA Organic Teas (the Green Tea and Rooibos Tea). "Nevada Department of Agriculture". As we are in a competitive market, we wish this certifier and our manufacturer of this product to remain confidential.

Sincerely,

Dr. Bartell

From:	drbartell@serenigy.com	
To:	Mann, Renee	
Subject:	Questions	
Date:	Tuesday, January 04, 2011 5:41:27 PM	

OK, Renee, Great that is all of them. Do you have any idea how long the process may be before we hear anything back on the letter and the approval of the corrections?

Also, our number one competitor is far from being compliant regarding the USDA organic claims on their products and I would like to file a complaint. How do I do this?

Thank you,

Dr. Bartell

Hello Dr. Bartell:

Thank you, I did receive the document. We are formulating a response. I will be in touch with you.

Kind Regards, Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Monday, December 12, 2011 12:14 PM To: Mann, Renee - AMS Subject: [FWD: RE: Fraudulent Organic Certificate]

Hello Renee,

Did you get this email reply I sent to you last week?

Thank you,

Dr. Bartell

------ Original Message ------Subject: RE: Fraudulent Organic Certificate From: <<u>drbartell@serenigy.com</u>> Date: Wed, December 07, 2011 7:25 pm To: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Cc: "Dr. Patel" <<u>dpatel@atlas-bioscience.com</u>>, "Suzy Guillory" <<u>squillory@serenigy.com</u>>, "Morgan Tharpe" <<u>mtharpe@serenigy.com</u>>

Hello Renee,

Atlas Bioscience laboratory has done testing on our products for nutrient content as well as other tests as per our request. As a part of this process, Atlas has also reviewed and confirmed the organic certification of the USDA certified ganoderma certificates of Analysis from (b) (4) through QAI as SereniGy's source of the ganoderma herb we use in all of our products that contain this herb confirming it is indeed a USDA certified organic source. That was the only intended purpose of this document which I requested Atlas provide the document with such a statement. The statement on the document is accurate and it was not intended to indicate that SereniGy as a company is certified by the USDA through Atlas as we are not the source of the ganoderma.

Our goal is to provide our customers and distributors some validation that we use only a USDA certified organic source of ganoderma which we do. However our source for the herb is proprietary and therefore we can not post the (b)(4) QAI certification document and reveal our manufacturer.

I had the document taken down immediately from our website as soon as I received your email until I have clarification from you as to how we can correct this to provide a third party laboratory validation that our ganoderma has been confirmed as a certified source without revealing our source of the herb. There

must be some way to show the public validation we use a certified organic herbal source in our product without revealing our source. If you have any solution or suggestion as to how this can be accomplished or what wording would need to be changed on the document I would greatly appreciate it.

Thank you,

Dr. Bartell 918-724-4974

cc Dr. Dinesh Patel cc Ms. Suzy Guilory cc Mr. Morgan Tharpe

> ------ Original Message ------Subject: Fraudulent Organic Certificate From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 07, 2011 3:28 pm To: "drbartell@serenigy.com" <<u>drbartell@serenigy.com</u>>

Dear Dr Bartell:

The United States Department of Agriculture's (USDA) <u>National Organic</u> <u>Program</u> (NOP) has identified a fraudulent certificate on the SereniGy Global, Inc. website: <u>http://www.serenigy.com/en/product/product-</u> <u>overview</u>. The certificate appears to have been produced by Atlas Bioscience, Inc. This certificate represents SereniGy Global, Inc. as having achieved "organic certification." The certification of companies is granted by certification agencies that are accredited by the USDA NOP. It does not appear that Atlas Bioscience, Inc. is an accredited certification agency.

Please contact me within the next 24 hours with an explanation as to why this certificate exists on the SereniGy website. If I do not hear from you by 6p.m. Eastern Standard Time on December 8, 2011, the NOP will proceed with posting this fraudulent certificate on its website with a warning to consumers.

Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division <u>National Organic Program</u> (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

From:	drbartell@serenigy.com
To:	Mann, Renee - AMS
Cc:	Suzy Guillory; Morgan Tharpe
Subject:	RE: [FWD: RE: Fraudulent Organic Certificate]
Date:	Monday, December 12, 2011 1:39:50 PM

Thank you.

------ Original Message ------Subject: RE: [FWD: RE: Fraudulent Organic Certificate] From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Mon, December 12, 2011 11:11 am To: "<u>drbartell@serenigy.com</u>" <<u>drbartell@serenigy.com</u>>

Hello Dr. Bartell:

Thank you, I did receive the document. We are formulating a response. I will be in touch with you.

Kind Regards, Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Monday, December 12, 2011 12:14 PM To: Mann, Renee - AMS Subject: [FWD: RE: Fraudulent Organic Certificate]

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through QAI as SereniGy's source of the ganoderma herb we use in all of our products that contain this herb confirming it is indeed a USDA certified organic source. That was the only intended purpose of this document which I requested Atlas provide the document with such a statement. The statement on the document is accurate and it was not
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Dr. Bartell 918-724-4974

cc Dr. Dinesh Patel cc Ms. Suzy Guilory cc Mr. Morgan Tharpe

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http://www.serenigy.com/en/product/product-overview. The certificate appears to have been produced by Atlas Bioscience, Inc. This certificate represents SereniGy Global, Inc. as having achieved "organic certification." The certification of companies is granted by certification agencies that are accredited by the USDA NOP. It does not appear that Atlas Bioscience, Inc. is an accredited certification agency.

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Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

#### Hello Renee,

I am letting you know that I am working on finding your answer. I'll get back to you as soon as possible.

# Carey Allen

Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Wednesday, February 22, 2012 2:37 PM To: Terrell, Joe Subject: (b)(4) / SereniGy

Dear Mr. Terrell,

I apologize for the email and for being in a rush, but I am working under a deadline and hope to get a quick answer. Please see the email below, which I sent to Mr. Morr. I understand from Mr. Morr's automatic reply that he is out of the office and I hope that you can help me.

Thank you, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Dear Mr. Morr:

I need a quick answer to a question involving (b)(4) I am looking at labels for SereniGy Global, a company that appears to have private labeled products produced by (b)(4) I was previously in contact with Maria DeVincenzo. At the time, it appeared that SereniGy's products were not certified, but they carried the USDA seal and the QAI seal. Now, the products do not carry the USDA seal but they do carry QAI's seal and state that they are all certified by QAI. Can you please confirm that the following products are now certified by QAI:

- 1. Slim Dietary Supplement (label claim is "made with organic ganoderma")
- 2. Time Capsule Herbal Supplement (label claim is "made with organic ganoderma")
- 3. Essential Herbal Supplement (label claim is "made with organic ganoderma")

All of the above products contain organic ganoderma and all three claim "made with organic ganoderma" on the front panel. The company listed on the product label is SereniGy Global, Inc., 201 South Biscayne Blvd., Suite #2800, Miami, FL 33131. Please let me know if you have any questions.

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### Hello Renee,

QAI does certify #2 and #3, but #1 is using the 'Q' mark without authorization because this product was not listed on the Product Summary. It is only listed for (0)(4) as 'non-retail'

- Slim Dietary Supplement (label claim is "made with organic ganoderma") Under (b)(4)
   ID Mark (non-retail "Slim Dried Full Spectrum Mushroom Powder", so this SereniGy product using "Q" mark is not authorized)
- 2. Time Capsule Herbal Supplement (label claim is "made with organic ganoderma") Certified by QAI as "SereniGy" Product ID Mark private label
- 3. Essential Herbal Supplement (label claim is "made with organic ganoderma") Certified by QAI as "SereniGy" Product ID Mark private label

Thank you for the information. I will follow up with the Q team on this for further action.

### Carey Allen

Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Wednesday, February 22, 2012 2:46 PM To: Allen, Carey Cc: Terrell, Joe; Morr, Craig Subject: RE: (b)(4) / SereniGy

Thank you so much Carey!

From: Allen, Carey [mailto:callen@nsf.org] Sent: Wednesday, February 22, 2012 2:44 PM To: Mann, Renee - AMS Cc: Terrell, Joe; Morr, Craig Subject: RE: <sup>(b)(4)</sup> / SereniGy

Hello Renee, I am letting you know that I am working on finding your answer. I'll get back to you as soon as possible.

*Carey Allen* Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Wednesday, February 22, 2012 2:37 PM To: Terrell, Joe Subject: (b)(4) / SereniGy

Dear Mr. Terrell,

I apologize for the email and for being in a rush, but I am working under a deadline and hope to get a quick answer. Please see the email below, which I sent to Mr. Morr. I understand from Mr. Morr's automatic reply that he is out of the office and I hope that you can help me.

Thank you, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

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From:	Mann, Renee - AMS
То:	<u>"Allen, Carey"</u>
Cc:	Terrell, Joe; Morr, Craig
Subject:	RE: (b)(4) / SereniGy
Date:	Wednesday, February 22, 2012 2:45:00 PM

Thank you so much Carey!

From: Allen, Carey [mailto:callen@nsf.org] Sent: Wednesday, February 22, 2012 2:44 PM To: Mann, Renee - AMS Cc: Terrell, Joe; Morr, Craig Subject: RE: (b)(4) / SereniGy

Hello Renee,

I am letting you know that I am working on finding your answer. I'll get back to you as soon as possible.

*Carey Allen* Quality Specialist Quality Assurance International NSF International 734 214 6261 <u>callen@nsf.org</u>

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Wednesday, February 22, 2012 2:37 PM To: Terrell, Joe Subject: (b)(4) / SereniGy

Dear Mr. Terrell,

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Thank you, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Dear Mr. Morr:

I need a quick answer to a question involving **(b)(4)**. I am looking at labels for SereniGy Global, a company that appears to have private labeled products produced by **(b)(4)**. I was previously in contact with Maria DeVincenzo. At the time, it appeared that SereniGy's products

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From:	Allen, Carey
To:	Mann, Renee - AMS
Subject:	RE: (b) (4) / SereniGy
Date:	Thursday, March 08, 2012 1:15:28 PM

Renee,

Regarding this SereniGy slim product discussed below, I am in contact with the client about the issue. (b) (4) inspection is upcoming and we've put a note it to include investigation into the sales of this item.

Do you need further information about this at this time, or should I update you on it after the investigation and any non-compliance has been determined?

Carey Allen

Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Thursday, February 23, 2012 2:47 PM To: Allen, Carey Cc: Morr, Craig Subject: RE: (b) (4) / SereniGy

Hi Carey,

Thank you so much for your response. Attached is the SereniGy Slim label. Please let me know if you have any trouble opening the attachment.

Kind Regards, Renee

From: Allen, Carey [mailto:callen@nsf.org] Sent: Wednesday, February 22, 2012 3:12 PM To: Mann, Renee - AMS Cc: Morr, Craig Subject: RE: (b) (4) / SereniGy

Hello Renee,

QAI does certify #2 and #3, but #1 is using the 'Q' mark without authorization because this product was not listed on the Product Summary. It is only listed for (b)(4) as 'non-retail'

- Slim Dietary Supplement (label claim is "made with organic ganoderma") Under (b)(4)
   ID Mark (non-retail "Slim Dried Full Spectrum Mushroom Powder", so this SereniGy product using "Q" mark is not authorized)
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- 3. Essential Herbal Supplement (label claim is "made with organic ganoderma") Certified by

QAI as "SereniGy" Product ID Mark private label

Thank you for the information. I will follow up with the Q team on this for further action.

*Carey Allen* Quality Specialist Quality Assurance International NSF International 734 214 6261 <u>callen@nsf.org</u>

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Wednesday, February 22, 2012 2:46 PM To: Allen, Carey Cc: Terrell, Joe; Morr, Craig Subject: RE: (b) (4) / SereniGy

Thank you so much Carey!

From: Allen, Carey [mailto:callen@nsf.org] Sent: Wednesday, February 22, 2012 2:44 PM To: Mann, Renee - AMS Cc: Terrell, Joe; Morr, Craig Subject: RE: (b) (4) / SereniGy

Hello Renee, I am letting you know that I am working on finding your answer. I'll get back to you as soon as possible.

*Carey Allen* Quality Specialist Quality Assurance International NSF International 734 214 6261 <u>callen@nsf.org</u>

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Wednesday, February 22, 2012 2:37 PM To: Terrell, Joe Subject: (b) (4) / SereniGy

Dear Mr. Terrell,

I apologize for the email and for being in a rush, but I am working under a deadline and hope to get a quick answer. Please see the email below, which I sent to Mr. Morr. I understand from Mr. Morr's automatic reply that he is out of the office and I hope that you can help me.

Thank you,

Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Dear Mr. Morr:

I need a quick answer to a question involving (b) (4) . I am looking at labels for SereniGy Global, a company that appears to have private labeled products produced by (b) (4) . I was previously in contact with Maria DeVincenzo. At the time, it appeared that SereniGy's products were not certified, but they carried the USDA seal and the QAI seal. Now, the products do not carry the USDA seal but they do carry QAI's seal and state that they are all certified by QAI. Can you please confirm that the following products are now certified by QAI:

- 1. Slim Dietary Supplement (label claim is "made with organic ganoderma")
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All of the above products contain organic ganoderma and all three claim "made with organic ganoderma" on the front panel. The company listed on the product label is SereniGy Global, Inc., 201 South Biscayne Blvd., Suite #2800, Miami, FL 33131. Please let me know if you have any questions.

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1. The inspection is scheduled for March 27, 2012

Product ID Mark is the "brand name" of the certified product, normally a retail product. Non-retail means (b)(4) makes it and packages it in bulk for use as a certified organic ingredient in other items.
 From what I can determine with the information available they were testing the finalized formula for the product at another facility (1000)(4) where it will be tableted and bottled. The label approval was in process with (b)(4) certifier, and the product was in process to be added to (b)(4) certification with their renewal as a MWO product.

I am still gathering information from <sup>(b)(4)</sup> about <sup>(b)(4)</sup> certifier, they are not listed with the NOP. I am not sure why they would be needing label approval, I don't see a connection between SereniGy and <sup>(b)(4)</sup>

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Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

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- 1. On what date (or around what date) is the (b)(4) inspection scheduled?
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Thanks for your thoughts. If you have any questions, please let me know.

Kind Regards, Renee Sent: Thursday, March 08, 2012 1:13 PM To: Mann, Renee - AMS Subject: RE: (b)(4) / SereniGy

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Do you need further information about this at this time, or should I update you on it after the investigation and any non-compliance has been determined?

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Hi Carey,

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Kind Regards, Renee

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# Hello Renee,

QAI does certify #2 and #3, but #1 is using the 'Q' mark without authorization because this product was not listed on the Product Summary. It is only listed for (b)(4) as 'non-retail'

- Slim Dietary Supplement (label claim is "made with organic ganoderma") Under (b)(4)
   ID Mark (non-retail "Slim Dried Full Spectrum Mushroom Powder", so this SereniGy product using "Q" mark is not authorized)
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Thank you, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Dear Mr. Morr:

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#### Renee,

I have gathered more evidence from <sup>(b)(4)</sup> regarding the Slim product. It appears that <sup>(b)(4)</sup> produced the tableted packaged Slim product for SereniGy at the <sup>(b)(4)</sup> co-packer, purportedly as a 'test', and then sold the 'test' product to SereniGy as an approved item prior to its actual formulation being reviewed and approved by QAI as a 'MWO' product. It was a PO fulfillment shipment, not just a sample shipment that inadvertently got put on the 'store' shelf as an approved item.

While I feel that we have the evidence to issue adverse action now, I prefer to manage it through the inspection review process in order to capture anything further that the inspector may find. From what I can tell, SereniGy does not appear to be complicit.

(b)(4) has received approval of the tableted Slim product just today from Organic Certifiers, however QAI has yet to approve the item for (b)(4) certificate.

Let me know if you need anything further at this time,

### Carey Allen

Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Monday, March 12, 2012 4:25 PM To: Allen, Carey Subject: RE: (()(4) / SereniGy

Dear Carey,

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- 1. On what date (or around what date) is the (b)(4) inspection scheduled?
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- 3. Also, do you have any evidence yet regarding the nature of the violation here, besides the fact that QAI did not approve of the Slim label? Do you know that the Slim product is made at the (b)(4) facility and made of organic ingredients, but simply not included in (b)(4) OSP as a private label item? Is there more that QAI is worried about, such as Serenigy creating this product on its own and (b)(4) having nothing to do with the Slim label?

Thanks for your thoughts. If you have any questions, please let me know.

Kind Regards,

Renee

From: Allen, Carey [mailto:callen@nsf.org] Sent: Thursday, March 08, 2012 1:13 PM To: Mann, Renee - AMS Subject: RE: (b)(4) / SereniGy

Renee,

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Do you need further information about this at this time, or should I update you on it after the investigation and any non-compliance has been determined?

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QAI does certify #2 and #3, but #1 is using the 'Q' mark without authorization because this product was not listed on the Product Summary. It is only listed for Aloha as 'non-retail'

Slim Dietary Supplement (label claim is "made with organic ganoderma") – Under <sup>(b)(4)</sup>
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### Carey Allen

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From:	<u>DeVincenzo, Maria</u>
To:	Mann, Renee
Subject:	RE: Attachments
Date:	Thursday, January 13, 2011 2:07:02 PM
Attachments:	(b) (4) Summary.pdf
	Approved Red Rishi labels - (b) (4)

Here is a copy of the email sent on Monday. We will contact (b) (4) to confirm if they are labeling the SereniGy Product or not. I did send SereniGy a cease & desist letter on Tuesday. I have not received a response from them. I will get back to you with any additional information I find.

Please confirm that you received this email. Thanks.

Hi Renee,

The 4 "SereniGy"product labels have been received. I have reviewed them and those products are not certified by QAI.

I checked our database for (b)(4) we do not certify any company by that name.

Per our conversation earlier today I am attaching a copy of the <sup>(b) (4)</sup> "Organic System Plan Summary (OSPS)" and the two product labels for the certified Red Reishi (Ganoderma lucidum) product(s), (ID marks, Reishi Essence and <sup>(b) (4)</sup> that are certified under the <sup>(b) (4)</sup> with Organic " claim on page 5 of the OSPS.

Thank you for bringing this to our attention. I will be sending SereniGy Global, Inc. a cease and desist letter regarding the use of the QAI logo this week.

Regards,

Maria DeVincenzo Quality Specialist Quality Assurance International 9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 USA (858) 200-9727 Phone (734) 827-6177 Fax www.qai-inc.com

please don't print this e-mail unless you really need to

Privacy Warning: This e-mail is the property of Quality Assurance International (QAI), a division of NSF International. It is intended only for the person or entity to which it is addressed and may contain information that is privileged, confidential, or otherwise protected from disclosure. Distribution or copying of this email, or the information contained herein to anyone other than the intended recipient is prohibited. It you have received this e-mail in error, please immediately notify the sender by e-mail at the address from which it has been sent. Please delete and destroy any copies of this e-mail.

From: Mann, Renee [mailto:Renee.Mann@ams.usda.gov] Sent: Thursday, January 06, 2011 3:22 PM To: DeVincenzo, Maria Subject: Attachments

Hi Maria,

I'm sorry about the various emails; that was probably confusing. At first, I thought one email would go through with all 4 attachments, and then maybe 2 at a time, and ultimately I had to send the 3.5MB attachment separately. So, ultimately, you should have four different labels for the following products:

- 1. Time
- 2. Essential
- 3. Slim
- 4. Fruit & Veggie Power Plus

Please let me know if you received all of these labels.

Thanks,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <u>http://bit.ly/NOPOrganicInsiderRegistration</u>

 From:
 drbartell@serenigy.com

 To:
 Mann, Renee - AMS

 Subject:
 Re: Case Closure and via Settlement Agreement

 Date:
 Wednesday, January 11, 2012 1:59:11 PM

Dr. Kent Bartell 121 S. 2nd St. Jenks, OK 74037 Sent from my U.S. Cellular BlackBerry® smartphone

From: "Mann, Renee - AMS" <Renee.Mann@ams.usda.gov> Date: Wed, 11 Jan 2012 17:54:01 +0000 To: 'drbartell@serenigy.com'<drbartell@serenigy.com> Subject: Re: Case Closure and via Settlement Agreement

Hello Dr. Bartell, I apologize but I do not have your exact address in Oklahoma. What is it? Thank You, Renee Mann ------Sent using BlackBerry

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Wednesday, January 11, 2012 10:48 AM
To: Mann, Renee - AMS
Subject: Re: Case Closure and via Settlement Agreement

Hello Renee,

Send it directly to me in Oklahoma will be fine. I am in meetings all day, but will contact you tomorrow regarding the issue once I have had time to review the documents and have spoken with our executives.

Thank you,

Dr. Bartell Sent from my U.S. Cellular BlackBerry® smartphone

From: "Mann, Renee - AMS" <Renee.Mann@ams.usda.gov> Date: Wed, 11 Jan 2012 16:22:35 +0000 To: drbartell@serenigy.com<drbartell@serenigy.com> Subject: RE: Case Closure and via Settlement Agreement

Dear Dr. Bartell:

I just left a message for you on your voicemail. If you have any questions about the settlement, please feel free to call me. Also, I am going to mail the original letter and the settlement agreement to you so that you may have the original documents. Should I send this to the 201 S. Biscayne Blvd Ste. 2800 Miami, Florida address or should I send this directly to you in Oklahoma?

Thank You, Renee Mann

From: Mann, Renee - AMS Sent: Tuesday, January 10, 2012 5:40 PM To: drbartell@serenigy.com Subject: Case Closure and via Settlement Agreement

Dear Dr. Bartell:

Thank you for your emails before the holidays explaining the attestation of organic status of the ganoderma on SereniGy's website. Attached please find two documents. One is a letter explaining the findings of the National Organic Program's (NOP) investigation of a complaint filed against SereniGy. The second is a settlement agreement that the NOP proposes in lieu of filing a formal administrative complaint against SereniGy.

SereniGy has two options in the case of this proposed settlement. SereniGy is free to not accept the settlement agreement. In that case, the case will move forward to an Adjudicative Law Judge of the USDA. SereniGy can also sign the agreement and send the civil penalty amount to the USDA as instructed. This second action would close the case against SereniGy and the National Organic Program would not pursue any further action against SereniGy based on the violations found last year.

To explain further, I should note that the complaint investigation is fairly straightforward. You and I discussed how the terms "certified," "100% organic," and similar phrases made your finished products seem as if they were being represented as certified organic. Thank you for working with me to explain SereniGy's purchase of organic ganoderma. Unfortunately, the organic program takes those claims very seriously, even if SereniGy did not mean to be in violation of the law. Also, the use of a document that looked like an organic certificate was taken very seriously. These main problem areas led the program to levy a civil penalty. I trust that the attached settlement agreement with a civil penalty of \$12,000 will be acceptable to SereniGy. We can issue \$11,000 per violation, which can be levied per product, per product sale, per label printed, or even per use of the term "organic." As you can see, the fines can get into the hundreds of thousands of dollars if you are fined \$11,000 for every product you sold with the word "organic!" However, I argued in SereniGy's favor, that it did not know what it had done was in error, and that it meant to only represent its certified organic ganoderma as organic. We also discussed how cooperative you were during the investigation, and how this was the first warning you would be receiving.

I hope we can close this out via settlement and get SereniGy on the road to always understanding the regulations and never having to hear from me again! I will call you tomorrow to confirm that you have received these documents and to answer any questions you may have.

Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

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Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

Hello Dr. Bartell,

Unfortunately, I did not receive the emails. Perhaps our spam guards filtered out the emails. Please try sending them again – maybe in smaller batches or in a zip file. I have had luck in the past receiving zipped documents.

Thank you,

Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:21 PM To: Mann, Renee Subject: Confirmation Request

Hello Renee,

I just wanted to confirm with you, did you receive my reply yesterday (3 emails total) with the 25 attached documents. RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Thank you,

Dr. Bartell

SereniGy VP Product R & D

Steve,

Thank you for speaking with me yesterday and for sending these documents to me so quickly. I will let you know if any additional information is required.

Kind Regards,

Renee Mann

From: Steve J. Marty [mailto:s\_marty@agri.state.nv.us] Sent: Tuesday, December 07, 2010 2:55 PM To: Mann, Renee Subject: (b)(4) SereniGy OPP and labels 120710.zip

Hello,

The approved Organic Product Profiles and labels as well as the non-compliant original labels for the (b) SereniGy products being packed by (b)(4) have been attached...sorry about the large file size. Please let me know if additioanl information is required. Thanks!
From:
 drbartell@serenigy.com

 To:
 Mann. Renee

 Subject:
 RE: File 15 of 25

 Date:
 Tuesday, January 04, 2011 5:27:04 PM

I sent these two in a smaller file size as a GIF picture format, please let me know if you received them.

Thank you,

Dr. Bartell

Barteli					
Original Message Subject: RE: File 15 of 25 From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> > Date: Tue, January 04, 2011 2:56 pm To: < <u>drbartell@serenigy.com</u> >					
Dr. Bartell,					
only received files 6 and 15.					
Renee					
From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 4:33 PM To: Mann, Renee Subject: File 15 of 25					
Original Message Subject: RE: Files 8 & 9 of 25 From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> > Date: Tue, January 04, 2011 2:11 pm To: < <u>drbartell@serenigy.com</u> >					
Dr. Bartell,					
It appears that I am missing the email with Files 6 & 7 and Files 14 & 15.					
Thank you,					
Renee					
From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:58 PM To: Mann, Renee Subject: Files 8 & 9 of 25					
Original Message Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> > Date: Tue, January 04, 2011 1:52 pm To: < <u>drbartell@serenigy.com</u> >					
Success!					
From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:50 PM To: Mann, Renee Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11]					
OK, I will see if two will go through. Please let me know if you get these.					
Thanks,					
Dr. Bartell Subject: RE: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11] From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> > Date: Tue, January 04, 2011 1:44 pm To: < <u>drbartell@serenigy.com</u> >					
Dr. Bartell,					
I received this email and its one attachment. You can send one attachment per email if you would like.					
Thank you,					

#### Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 3:35 PM To: Mann, Renee Subject: [FWD: RE: SereniGy, NOP Complaint Case Number NOPC-005-11]

Hello Renee,

OK, I'm glad I checked. This was the first email and I have removed all but one file. I will work to see if I can zip the files. Please confirm they come through. If I am unable, I can just send one attachement per email if that works also.

Thank you,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: <<u>drbartell@serenigy.com</u>> Date: Mon, January 03, 2011 2:21 pm To: "Mann,Renee" <<u>Renee.Mann@ams.usda.gov</u>>

Dear Renee,

We have made the label changes according to the USDA regulations. Here is a brief summary of the action we have taken for each of our 12 products.

Lightning: No label changes needed however we will re-word the web page to be clear we are making no organic claims with this product.

**Time & Essential:** These products contain over 70% by weight of certified organic herbs and the remaining weight is the non-certified and non-organic vegetable capsule. We have made label changes and will make web site changes to comply with the regulations. Certified by QAI, we have provided our manufacturer for organic status verification. The other option we are considering with these two products is to make the product as a caplet instead of a capsule. The caplet can be made with 100% organic ingredients and therefore we have included an "option 2" in the graphics for your review. Field product testing will be necessary before we make the decision to move forward on this. The labels are included for this option as well.

Green Tea and Rooibos Teas: These two products are certified 100% organic and we have provided the manufacturer for verification.

Gourmet Black Coffee, Latte, Mocha, Hot Chocolate, Chai Tea, Fruit & Veggie Power Plus, Slim: These seven products contain a very small amount of the ganoderma herbal product and so we have made the necessary modifications to the boxes and labels to be compliant and will also modify the web site graphics and text to also comply.

We request a 6 month time period to exhaust our current product inventory (06/30/2011).

We request 45 days from the date that NOP has given us approval on the corrected product labels and boxes we have provided to allow us time to make these corrected changes to the <u>SereniGy.com</u> web site.

Please find attached all the requested information and graphics files for our current labels and boxes and our revised labels and boxes. The file names indicate these as such. I may need to send the files in several attachment emails.

SereniGy Product Manufacturers: (Confidential Information)



Please confirm you have received this email.

Sincerely,

	Original Message
Fro	bject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 om: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> >
	te: Thu, December 30, 2010 8:33 am : < <u>drbartell@serenigy.com</u> >
De	ar Dr. Bartell:
lt i	s understandable that you need to know what your new labels will look like before revising
yo	ur website. This would be acceptable to revise the website after the January 3, 2011 deadline.
	u are not expected to accomplish everything by January 3 <sup>rd</sup> , but at least to have a plan for how
× .	ur company will come into compliance and reasons why you would need additional time. I look ward to hearing from you on January 3 <sup>rd</sup> .
101	ward to nearing norr you on January 5°.
Sin	cerely,
Re	nee Mann
	m: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
То	nt: Thursday, December 23, 2010 9:28 PM : Mann, Renee
Su	bject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11
He	Ilo Renee,
be ad lat ea gra inc	garding your request to provide the information as listed, #3 requests that the labels revised on our website to be compliant. I would like to request that we are given ditional time to make the website graphic changes once you have received our revised bels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to ch one. The reason for this is that it will take some IT work to replace all of the aphics files on the website and we would like to be sure that the revised graphics are leed acceptable and approved by NOP prior to posting all of them online. Would this acceptable?
Sir	ncerely,
	Bartell
5.	
	Original Message Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> > Date: Wed, December 08, 2010 10:56 am To: < <u>drbartell@serenigy.com</u> >
	Dear Dr. Bartell,
	I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.
	Sincerely,
	Renee Mann
	From: Mann, Renee
	Sent: Wednesday, December 08, 2010 12:16 PM To: <u>drbartell@serenigy.com</u>
	Subject: SereniGy, NOP Complaint Case Number NOPC-005-11
	Dear Dr. Bartell,
	It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production

	have identified several other products on your website that may have labeling violations, which we discussed.
	Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create labels that are compliant with the regulations. Pay specific attention to §205.100 <i>What has to be certified</i> , §205.101 <i>Exemptions and exclusions from certification</i> and Subpart D- <i>Labels, Labeling, and Market Information.</i> http://ecfr.gpoaccess.gov/cgi/t/text/text-idx? C=ecfr&sid=Ofdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7 If the above link does not work, you can also navigate to the regulations through the NOP website's Resource Center: http://www.ams.usda.gov/NOPResourceCenterRegulations In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010:
Si R Ic Si Pi	<ul> <li>bmit the current product labels, including information and display panels, for the following products:</li> <li>Gourmet Black Coffee</li> <li>Gourmet Mocha</li> <li>Gourmet Mocha</li> <li>Gourmet Chai Tea</li> <li>Organic Green Tea</li> <li>Gourmet Organic Rooibos Tea</li> <li>SG Ganoderma Essential</li> <li>SG Time Capsule</li> <li>SG Sim</li> <li>SereniGy Fruit &amp; Veggle Power Plus.</li> </ul> bmit revised labels for the abovementioned products that are compliant with the NOP regulations. evaluations. evaluations. wise the abovementioned labels on the website, and ensure that references to "organic certificate of the abovementioned products that processes and labels the finished product. bmit the organic certificate of the ganoderma that is used in the SereniGy products. product. products. product. products. product. products. product.
	If you have any questions, please feel free to contact me at (202) 205-5213 or renee.mann@ams.usda.gov. Also, please note that I will be on vacation from December 20 <sup>th</sup> through December 25 <sup>th</sup> . If I am unavailable, you may contact a representative of the NOP through the main NOP phone line at (202)720-3252. Sincerely, Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax Join the NOP mailing list at http://bit.ly/NOPOrganicInsiderRegistration

OK, I will try sending these 4 separately.

Thanks,

Dr. Bartell

Original Message Subject: RE: Files 8 & 9 of 25 From: "Mann, Renee" < <u>Renee.Mann@ams.usda.gov</u> > Date: Tue, January 04, 2011 2:11 pm To: < <u>drbartell@serenigy.com</u> >						
Dr. Bartell,						
It appears that I am missing the email with Files 6 & 7 and Files 14 & 15.						
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Renee						

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SereniGy Product Manufacturers: (Confidential Information)



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S	ncerely,
	r. Kent Bartell P Product R & D
•	
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W	verything by January 3 <sup>rd</sup> , but at least to have a plan for how your company ill come into compliance and reasons why you would need additional time. I
10	ok forward to hearing from you on January 3 <sup>rd</sup> .
Si	ncerely,
Re	enee Mann
	rom: <u>drbartell@serenigy.com</u> [mailto:drbartell@serenigy.com] ent: Thursday, December 23, 2010 9:28 PM
Т	: Mann, Renee ubject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11
Н	ello Renee,
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C	ncerely,
5	-

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Renee Mann

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Dear Dr. Bartell,

It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code of Federal Regulations, 7 CFR §205, National Organic Program.

Specifically, the complaint alleges that the Gourmet Black Coffee and Gourmet Latte are not certified as organic. Additionally, I have identified several other products on your website that may have labeling violations, which we discussed.

Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create labels that are compliant with the regulations. Pay specific attention to §205.100 What has to be certified, §205.101 Exemptions and exclusions from certification and Subpart D-Labels, Labeling, and Market Information. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx? c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7 If the above link does not work, you can also navigate to the regulations through the NOP website's Resource Center: http://www.ams.usda.gov/NOPResourceCenterRegulations In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010:

Submit the current product labels, including information and display panels, for the following products: Gourmet Black Coffee

Gourmet Latte Gourmet Mocha Gourmet Hot Chocolate Gourmet Chai Tea Organic Green Tea Gourmet Organic Rooibos Tea SG Ganoderma Essential SG Time Capsule SG Slim SereniGy Fruit & Veggie Power Plus. Supmit revised labels for the abovementioned products that are compliant with the NOP regulations. Revise the abovementioned labels on the website, and ensure that references to "organic" products or ingredients are in compliance with the NOP regulations. Identify the manufacturer of the abovementioned products that processes and labels the finished product. pmit the organic certificate of the ganoderma that is used in the SereniGy Su products. vide a proof of purchase of the ganoderma (by the manufacturer identified in number 3 above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4)(iii) records must be maintained by the exempt handling operation). nfirm that the Nutraceutical SG Lightning does not claim "organic" on its label. C You could meet this requirement by submitting the current product label. If you have any questions, please feel free to contact me at (202) 205-5213 or renee.mann@ams.usda.gov. Also, please note that I will be on vacation from December 20<sup>th</sup> through December 25<sup>th</sup>. If I am unavailable, you may contact a representative of the NOP through the main NOP phone line at (202)720-3252. Sincerely, Renee Mann **Compliance Specialist USDA National Organic Program** (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at http://bit.ly/NOPOrganicInsiderRegistration

From:	drbartell@serenigy.com
To:	Mann, Renee - AMS
Cc:	Dr. Patel; Suzy Guillory; Morgan Tharpe
Subject:	RE: Fraudulent Organic Certificate
Date:	Wednesday, December 07, 2011 9:25:08 PM
Attachments:	Atlas Organic Document.jpg

Hello Renee,

Atlas Bioscience laboratory has done testing on our products for nutrient content as well as other tests as per our request. As a part of this process, Atlas has also reviewed and confirmed the organic certification of the USDA certified ganoderma certificates of Analysis from (b)(4) through QAI as SereniGy's source of the ganoderma herb we use in all of our products that contain this herb confirming it is indeed a USDA certified organic source. That was the only intended purpose of this document which I requested Atlas provide the document with such a statement. The statement on the document is accurate and it was not intended to indicate that SereniGy as a company is certified by the USDA through Atlas as we are not the source of the ganoderma.

Our goal is to provide our customers and distributors some validation that we use only a USDA certified organic source of ganoderma which we do. However our source for the herb is proprietary and therefore we can not post the (b)(4) QAI certification document and reveal our manufacturer.

I had the document taken down immediately from our website as soon as I received your email until I have clarification from you as to how we can correct this to provide a third party laboratory validation that our ganoderma has been confirmed as a certified source without revealing our source of the herb. There must be some way to show the public validation we use a certified organic herbal source in our product without revealing our source. If you have any solution or suggestion as to how this can be accomplished or what wording would need to be changed on the document I would greatly appreciate it.

Thank you,

Dr. Bartell 918-724-4974

cc Dr. Dinesh Patel cc Ms. Suzy Guilory cc Mr. Morgan Tharpe

> ------ Original Message ------Subject: Fraudulent Organic Certificate From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 07, 2011 3:28 pm To: "<u>drbartell@serenigy.com</u>" <<u>drbartell@serenigy.com</u>>

Dear Dr Bartell:

The United States Department of Agriculture's (USDA) <u>National Organic Program</u> (NOP) has identified a fraudulent certificate on the SereniGy Global, Inc. website: <u>http://www.serenigy.com/en/product/product-overview</u>. The certificate appears to have been produced by Atlas Bioscience, Inc. This certificate represents SereniGy Global, Inc. as having achieved "organic certification." The certification of companies is granted by certification agencies that are accredited by the USDA NOP. It does not appear that Atlas Bioscience, Inc. is an accredited certification agency.

Please contact me within the next 24 hours with an explanation as to why this certificate exists on the SereniGy website. If I do not hear from you by 6p.m. Eastern Standard Time on December 8, 2011, the NOP will proceed with posting this fraudulent certificate on its website with a warning to consumers.

Sincerely, Renee Mann Compliance Specialist, Compliance & Enforcement Division <u>National Organic Program</u> (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

Dear Dr. Bartell:

Thank you for your letter of request, dated February 6, 2012. My supervisor and I have reviewed your letter in detail. We will consider lowering the civil penalty if you can demonstrate evidence of SereniGy's use of revised, compliant labels.

Please mail to us the products, physical labels (presumably on the products), and physical boxes that SereniGy currently uses. These should be the products, labels, and boxes that SereniGy currently uses to represent its products in the marketplace and that SereniGy currently uses when fulfilling customer orders for the products below.

- a. Gourmet Black Coffee
- b. Gourmet Latte
- c. Gourmet Mocha
- d. Gourmet Hot Chocolate
- e. Gourmet Chai Tea
- f. Essential
- g. Time Capsule
- h. Slim
- i. Fruit & Veggie Power Plus

These items must arrive at the USDA National Organic Program office by the end of the day on Tuesday, February 21, 2012, and should be mailed by Federal Express or UPS. The United States Postal Service is not reliable in our building and should not be used. The items should be mailed to the address below.

USDA-AMS-NOP Attn: Renee Mann 1400 Independence Ave. SW Mail Stop 0268, Room 2957 Washington, DC 20250

Thank you for your attention to this matter. If you have any questions, please feel free to contact me at (202) 205-5213.

Sincerely, Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Monday, February 06, 2012 11:11 PM To: Mann, Renee - AMS Cc: Suzy Guillory Subject: NOP Request for Review

Hello Renee,

Please see the attached letter with the request for a review of our case. Please confirm you have received my request.

Thank you so much for your help,

Dr. Bartell

cc Ms. Suzy Guillory

Hello Renee,

I personally am in the process of collecting the printed packaging (boxes and bottles) for the products and you will receive them by the date requested.

Thank you,

Dr. Bartell

cc Ms. Suzy Guillory

------ Original Message ------Subject: RE: NOP Request for Review From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, February 15, 2012 8:58 am To: "<u>drbartell@serenigy.com</u>" <<u>drbartell@serenigy.com</u>> Cc: Suzy Guillory <<u>sguillory@serenigy.com</u>>

Dear Dr. Bartell:

Thank you for your letter of request, dated February 6, 2012. My supervisor and I have reviewed your letter in detail. We will consider lowering the civil penalty if you can demonstrate evidence of SereniGy's use of revised, compliant labels.

Please mail to us the products, physical labels (presumably on the products), and physical boxes that SereniGy currently uses. These should be the products, labels, and boxes that SereniGy currently uses to represent its products in the marketplace and that SereniGy currently uses when fulfilling customer orders for the products below.

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USDA-AMS-NOP Attn: Renee Mann 1400 Independence Ave. SW Mail Stop 0268, Room 2957 Washington, DC 20250

Thank you for your attention to this matter. If you have any questions, please feel free to contact me at (202) 205-5213.

Sincerely, Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Monday, February 06, 2012 11:11 PM
To: Mann, Renee - AMS
Cc: Suzy Guillory
Subject: NOP Request for Review

Hello Renee,

Please see the attached letter with the request for a review of our case. Please confirm you have received my request.

Thank you so much for your help,

Dr. Bartell

#### cc Ms. Suzy Guillory

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

From:	drbartell@serenigy.com
To:	Mann, Renee - AMS
Cc:	Suzy Guillory
Subject:	RE: NOP Request for Review
Date:	Monday, February 20, 2012 4:46:38 PM

Hello Renee,

I have personally sent the package from my office New Hope Health Clinic with the requested revised compliant labels and packaging for the 9 SereniGy products in review via the UPS Tracking number <sup>(b)(4)</sup>

This package will be delivered via overnight delivery to the USDA - NOP address given and arrive tomorrow February 21st as requested.

Thank you,

Dr. Bartell

cc Ms. Suzy Guillory

------ Original Message ------Subject: RE: NOP Request for Review From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, February 15, 2012 8:58 am To: "<u>drbartell@serenigy.com</u>" <<u>drbartell@serenigy.com</u>> Cc: Suzy Guillory <<u>sguillory@serenigy.com</u>>

Dear Dr. Bartell:

Thank you for your letter of request, dated February 6, 2012. My supervisor and I have reviewed your letter in detail. We will consider lowering the civil penalty if you can demonstrate evidence of SereniGy's use of revised, compliant labels.

Please mail to us the products, physical labels (presumably on the products), and physical boxes that SereniGy currently uses. These should be the products, labels, and boxes that SereniGy currently uses to represent its products in the marketplace and that SereniGy currently uses when fulfilling customer orders for the products below.

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Thank you for your attention to this matter. If you have any questions, please feel free to contact me at (202) 205-5213.

Sincerely, Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Monday, February 06, 2012 11:11 PM To: Mann, Renee - AMS Cc: Suzy Guillory

Subject: NOP Request for Review

Hello Renee,

Please see the attached letter with the request for a review of our case. Please confirm you have received my request.

Thank you so much for your help,

Dr. Bartell

cc Ms. Suzy Guillory

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Dear Dr. Bartell,

Thank you for sending the packages. We are in the process of reviewing the packages and providing a formal response. I will be in contact with you. Thank you for your patience.

Kind Regards, Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Friday, March 09, 2012 11:41 PM
To: Mann, Renee - AMS
Cc: Suzy Guillory
Subject: RE: NOP Request for Review

Hello Renee,

We see the packaging of all our products in question had arrived as requested on Feb. 21st 2012 and were wondering if there was a conclusion or decision yet on our case. Thank you for your consideration in this matter.

Dr. Bartell

cc Ms. Suzy Guillory

------ Original Message ------Subject: RE: NOP Request for Review From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, February 15, 2012 8:58 am To: "<u>drbartell@serenigy.com</u>" <<u>drbartell@serenigy.com</u>> Cc: Suzy Guillory <<u>squillory@serenigy.com</u>>

Dear Dr. Bartell:

Thank you for your letter of request, dated February 6, 2012. My supervisor and I have reviewed your letter in detail. We will consider lowering the civil penalty if you can demonstrate evidence of SereniGy's use of revised, compliant labels.

Please mail to us the products, physical labels (presumably on the products), and physical boxes that SereniGy currently uses. These should be the products, labels, and boxes that SereniGy currently uses to represent its products in the marketplace and that SereniGy currently uses when fulfilling customer orders for the products below.

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These items must arrive at the USDA National Organic Program office by the end of the day on Tuesday, February 21, 2012, and should be mailed by Federal Express or UPS. The United States Postal Service is not reliable in our building and should not be used. The items should be mailed to the address below.

USDA-AMS-NOP Attn: Renee Mann 1400 Independence Ave. SW Mail Stop 0268, Room 2957 Washington, DC 20250

Thank you for your attention to this matter. If you have any questions, please feel free to contact me at (202) 205-5213.

Sincerely, Renee Mann

From: <u>drbartell@serenigy.com</u> [mailto:drbartell@serenigy.com]

Sent: Monday, February 06, 2012 11:11 PM To: Mann, Renee - AMS Cc: Suzy Guillory Subject: NOP Request for Review

Hello Renee,

Please see the attached letter with the request for a review of our case. Please confirm you have received my request.

Thank you so much for your help,

Dr. Bartell

cc Ms. Suzy Guillory

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Thank you Renee. I appreciate your help in this matter.

Kind Regards,

Suzy Guillory SereniGy Global Inc. Vice President of Corporate Development 201 S Biscayne Blvd Ste 2800 Miami, FL 33131 720-422-1032

This e-mail communication is confidential and may be subject to solicitor/client privilege. If you are not the intended recipient, please notify me at the telephone number shown above or by return e-mail and delete this communication and any copy. Thank you.

------ Original Message ------Subject: Re: NOP Request for Review From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Tue, February 07, 2012 5:53 am To: "'<u>drbartell@serenigy.com</u>'" <<u>drbartell@serenigy.com</u>> Cc: "'<u>sguillory@serenigy.com</u>'" <<u>sguillory@serenigy.com</u>> Dear Dr. Bartell,

Thank you for the letter. I will be in contact with you. Sincerely, Renee Mann

Sent using BlackBerry

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Monday, February 06, 2012 10:11 PM To: Mann, Renee - AMS Cc: Suzy Guillory <<u>sguillory@serenigy.com</u>> Subject: NOP Request for Review

Hello Renee,

Please see the attached letter with the request for a review of our case. Please confirm you have received my request.

Thank you so much for your help,

Dr. Bartell

#### cc Ms. Suzy Guillory

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Hello Dr. Bartell,

Thank you for speaking with me yesterday regarding the SereniGy products. I haven't yet had time to write an entire synopsis of the situation, but because you were concerned about who I contacted regarding the complaint, I thought I would quickly give you a list of who I contacted:

- (b)(6),(b)(7)(c),(b)(7)(d)
- (b)(6).(b)(7)(c).(b)(7)(d)
- (b)(6),(b)(7)(c),(b)(7)(d)

I will be in contact regarding the rest of the conversation that we had within the next day.

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Monday, December 06, 2010 4:54 PM
To: Mann, Renee
Subject: Organic Certification for our Teas

Hello Renee,

It was a pleasure and informative speaking with you this afternoon regarding our labels. Here is our certifier for our USDA Organic Teas (the Green Tea and Rooibos Tea). "Nevada Department of Agriculture". As we are in a competitive market, we wish this certifier and our manufacturer of this product to remain confidential.

Sincerely,

Dr. Bartell

### Dear Dr. Bartell,

Thank you for ensuring that I received all of the attachments. I was able to open all of the attachments. At the longest, you should expect to hear back from me in two weeks. Hopefully I will be able to review them quickly, so it should not take that long.

If you would like to submit a complaint, please submit your complaint to <u>NOPCompliance@ams.usda.gov</u>. You can also mail your complaint in, but most people choose to email their complaints. If you would like information on filing a complaint, please visit <u>http://www.ams.usda.gov/AMSv1.0/NOPFileaComplaint</u>. Also, if you have any specific questions before filing your complaint, you can contact me and I can help answer those questions.

Kind Regards,

Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Tuesday, January 04, 2011 5:41 PM To: Mann, Renee Subject: Questions

OK, Renee, Great that is all of them. Do you have any idea how long the process may be before we hear anything back on the letter and the approval of the corrections?

Also, our number one competitor is far from being compliant regarding the USDA organic claims on their products and I would like to file a complaint. How do I do this?

Thank you,

Dr. Bartell

Hello Renee,

Thank you for your help. I am working diligently on this and I understand we need to have (b)(4) in the certifying process with QAI when I submit these new labels to you. I can assure you (b)(4) will be getting our products "Time" and "Essential" certified by QAI as they already have their own brand of essentially the same products certified and it is basically a labeling issue (our private label) and not a product or manufacturing issue.

In addition, as I had mentioned previously in the first response, we are in the process of having<sup>(b)(4)</sup> produce a completely organic tablet of each of these three as well which will also be certified by QAI and thus we will be able to also use the USDA seal on the three products produced by <sup>(b)(4)</sup> "Slim" "Time" and "Essential". This is why I also sent to you the alternate labels that indicated "caplets" (a slender form of a tablet) instead of the current capsules. Our next PO with<sup>(b)(4)</sup> on any of these three products will have only the corrected and approved labels by QAI and by you at NOP with the capsules, tablets, or caplets (prior to any PO being placed).

Thank you,

Dr. Bartell

------ Original Message ------Subject: RE: Response regarding organic labeling From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov>;</u> Date: Tue, February 01, 2011 1:23 pm To: <<u>drbartell@serenigy.com</u>>

Hello Dr. Bartell,

(0)(4) got some of their points right, but I find some of their statements confusing. Please see my comments in red.

1. 100% organic product in a capsule can not be claimed on the label as 100% organic anywhere other than in the ingredient list. (This is partially correct. Yes, it cannot say 100% organic if the capsule is not organic. Also, it shouldn't say 100% organic in the ingredient list. The ingredient list should just say "organic ganoderma" or whatever the organic ingredient is.) It must state 'Made with Organic X (X = name the ingredient)' providing the organic ingredient is 70% or more of the total weight. (Actually, this is true if the total of all ingredients (not just one) is at or over 70% of the product AND the finished product must be certified.)

2. Tablets will need to carry an ingredient list organic claim due to the tableting Excipients, and in your case, Rhodiola not being an organic ingredient. However we are currently working on producing a tablet with organic excipients – we will have this completed soon. (The FDA requires that the label disclose certain ingredients. The NOP requires that the organic ingredients be disclosed. You must make sure that you follow all applicable regulations.) 3. No printed material or information between the 'Certified by QAI' statement and the distributor's address and contact info. (This is true. However, if the entire product is not certified by QAI then they won't let you use their seal at all.)

4. "Made with Organic" products are not to display the USDA logo. True.

5. You can use the QAI logo on encapsulated products but it has to say 'Made with Organic (ingredient)' as explained in #1 below. (This is true if the product is at least 70% organic ingredients. Also, the finished product must be certified.)

6. You can not use the USDA logo anywhere b/c they are not 100% organic. (Kind of true. Yes, you can only use the USDA seal with products that are 95% and higher organic content, not just 100% organic. The finished product must also be certified.)

You may want to review this fact sheet on organic labeling: <u>http://www.ams.usda.gov/AMSv1.0/getfile?</u>

dDocName=STELDEV3004446&acct=nopgeninfo

Regarding your questions surrounding the labeling, you do have a cart before the horse situation going on here. If you can prove to the NOP that you are in the process of getting the products certified and you can submit labels that are compliant with the NOP regulations (as if your products were currently certified) then I may be able to close the case on my end. If you don't move forward quickly enough with getting the labels certified (or you decide not to get the products certified), then I would still have to ask you to submit fully compliant labels to me, and I would treat your products as if they weren't certified. In that case, you would have to remove all references to QAI and the QAI logo. So, it just depends on how quickly you act to get the products certified. You should talk to QAI because it may be as simple as having them review your labels, but I gathered from QAI that Aloha Medicinals has only one facility that is certified and your products are not produced in that facility, so this could drag out the process of certification.

I would guess that you will still have questions about this, because this is a complex situation. Please call me if you would like to discuss the above points. I am in the office this week and can be reached at 202-205-5213 from 8am to 5:30pm Eastern.

Kind Regards,

Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Monday, January 31, 2011 6:18 PM To: Mann, Renee Subject: RE: Response regarding organic labeling

Hello Renee,

Thank you for calling me back last week. It looks like I may have missed you

again today. I would like your input regarding the QAI logo use. The QAI certified organic manufacturer that we use for our Slim, Time and Essential products (p)(4)

has provided us with this guideline for the use of the QAI logo. I want to be sure it is accurate before I proceed with labeling changes to submit to you and for <sup>(b)(4)</sup> to also submit to QAI. I expect we need to have the QAI logo on the labels to submit to them to QAI and once approved to then submit them to NOP. Is this correct? If so, we may need more time to first have QAI certification approval then to submit to you. It seems like there are conflicting expectations here for us and I would like some clarification.

From <sup>(b)(4)</sup> who is QAI certified...

 100% organic product in a capsule can not be claimed on the label as 100% organic anywhere other than in the ingredient list. It must state 'Made with Organic X (X = name the ingredient)' providing the organic ingredient is 70% or more of the total weight.
 Tablets will need to carry an ingredient list organic claim due to the tableting Excipients, and in your case, Rhodiola not being an organic ingredient. However we are currently working on producing a tablet with organic excipients – we will have this completed soon.

3. No printed material or information between the 'Certified by QAI' statement and the distributor's address and contact info.

4. "Made with Organic" products are not to display the USDA logo.

5. You can use the QAI logo on encapsulated products but it has to say 'Made with Organic (ingredient)' as explained in #1 below

6. You can not use the USDA logo anywhere b/c they are not 100% organic.

Thank you,

Dr. Bartell

------ Original Message ------Subject: Response regarding organic labeling From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov>;</u> Date: Thu, January 27, 2011 12:12 pm To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

Thank you for submitting your response on January 3, 2011 to the NOP regarding your various product labels that identify organic ingredients.

I have been in communication with Quality Assurance International (QAI) regarding the Time, Essential, and Slim labels. QAI issued a cease and desist notification to you because your labels cannot carry the QAI logo if your final product is not certified by QAI. To clarify, in order to display the USDA seal, the words "certified organic" or the QAI logo, the entire product would need to be certified as organic by QAI. Because only the ganoderma in the product is certified and the entire product is not certified, you cannot use the "certified organic" label claim, USDA seal or QAI logo. The finished product is certified only by being produced in an organic certified facility by a company that carries certification AND if the product labels have been reviewed and approved by the certification agency, such as QAI.

Please revise the supplement labels that contain references to QAI by removing the QAI logo and any reference to QAI. You can still obtain certification for these products in the future, but currently because the products are not certified, the labels must not display the QAI logo. To obtain certification, your supplier or you may work directly with a certifier, such as QAI, to obtain approval for the labels.

In relation to the Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate and Gourmet Chai Tea, the term "100% Certified" on the principal display panel (front panel) appears to reference the organic certification of the ganoderma ingredient. This is a violation of 7 CFR §205.100 and §205.305(a) because the claim could mislead customers to think that the entire coffee or tea product is 100% certified. Only products that are certified may be identified or represented as organic on the principal display panel. Please revise these labels again to remove the term "certified" and submit proofs to the NOP for review.

Thank you for providing the proof of purchase of the <sup>(b)(4)</sup> ganoderma product. In relation to your other manufacturers, please identify from what company the ganoderma is purchased that is subsequently used by <sup>(b)(4)</sup> and <sup>(b)(4)</sup> to manufacture the Serenigy products. QAI confirmed that <sup>(b)(4)</sup> carries certification for its ganoderma product but I need to confirm that the ganoderma going into all of your products is certified. If there is another source besides <sup>(b)(4)</sup> please provide the certificates for the additional ganoderma products and the proofs of purchase.

Please provide your response by February 18, 2011. If you have any questions, feel free to contact me at (202) 205-5213 or renee.mann@ams.usda.gov.

Sincerely,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at http://bit.ly/NOPOrganicInsiderRegistration

Hello Renee,

I have re-submitted the Slim, Time and Essential labels to you through (b)(4) yesterday as per your request as a "cc" with our submission to QAI. Today I have also sent you 6 revised graphic files which were the corrected Fruit & Veggie Label, Black coffee, Latte coffee, Mocha coffee, Hot Chocolate, and the Chai Tea for your review. Please confirm receipt of these emails or if you have any further questions regarding our compliance.

Thank you and have a great day,

Dr. Bartell

## Dear Carey,

Thank you for this information. We received the Slim product directly from SereniGy. They sent an empty bottle to my office, along with their other supplement product containers (with labels attached). It appears that the label I have is the one that is currently on the website too: <a href="http://serenigy.com/en-US/products/our-products/nutritional-supplements/slim-weight-control">http://serenigy.com/en-US/products/our-products/nutritional-supplements/slim-weight-control</a>. I asked SereniGy to provide the labels that they currently sell the product in.

Kind Regards, Renee

From: Allen, Carey [mailto:callen@nsf.org] Sent: Tuesday, March 13, 2012 3:42 PM To: Mann, Renee - AMS Subject: SereniGy - Slim

### Renee,

More information from <sup>(b)(4)</sup> regarding SereniGy. See below explanation of the tableter and the attached certificate. Additionally, the attached message from <sup>(b)(4)</sup> regarding the production trial. May I ask, did you obtain the Slim product from the SereniGy website?

# Carey Allen

Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

From: Orr, Emily Sent: Tuesday, March 13, 2012 2:41 PM To: Allen, Carey Subject: RE: SereniGy - Slim

Carey,

Organic Certifiers certifies <sup>(b)(4)</sup> I was informed by <sup>(b)(4)</sup> that this company is changing their name to <sup>(b)(4)</sup> <sup>(b)(4)</sup> <sup>(b)(4)</sup> is the company that encapsulates and packs the mushroom products that <sup>(b)(4)</sup> grows, including for the SereniGy ID Mark. <sup>(b)(4)</sup> works directly with <sup>(b)(4)</sup> with the product packaging. I don't know who her contact at SereniGy is. I have attached <sup>(b)(4)</sup> last email to me regarding this matter.

*Emily Orr* <u>eorr@qai-inc.com</u> P: (858)200-9337

# F: (734)827-7764

not necessarily represent those of NSF International or its affiliates.

Dear Dr. Bartell:

Thank you for the submissions. I have received all six of the emails and the email from <sup>(b)(4)</sup> (<sup>b)(4)</sup> yesterday. I will be in contact with you once I am able to review the labels.

Kind Regards,

Renee

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Friday, February 18, 2011 1:47 PM
To: Mann, Renee
Subject: SereniGy files have been sent

Hello Renee,

I have re-submitted the Slim, Time and Essential labels to you through (4) yesterday as per your request as a "cc" with our submission to QAI. Today I have also sent you 6 revised graphic files which were the corrected Fruit & Veggie Label, Black coffee, Latte coffee, Mocha coffee, Hot Chocolate, and the Chai Tea for your review. Please confirm receipt of these emails or if you have any further questions regarding our compliance.

Thank you and have a great day,

Dr. Bartell

of

Dear Dr. Bartell:

I spoke with Renee Mann about your phone conversation with her. The settlement agreement and civil penalty are still offered as stated in the March 15, 2012, letter.

Because March 31<sup>st</sup> falls on a Sunday, we will accept payment of the penalty next week.

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 <u>matthew.michael@ams.usda.gov</u>

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From: Michael, Matthew - AMS Sent: Wednesday, March 28, 2012 9:55 AM To: 'drbartell@serenigy.com' Cc: Mann, Renee - AMS Subject: SereniGy Response regarding the NOP Letter

Dear Dr. Bartell:

Thank you for your correspondence dated March 26, 2012. We understand your position regarding the noncompliances listed in my March 15, 2012, letter to you. If you agree to the terms of the settlement agreement, please sign the original and return it to the address noted in the letter by March 31, 2012, along with a certified check or money order made payable to the "Treasurer of the United States."

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 <u>matthew.michael@ams.usda.gov</u>

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Dear Dr. Bartell:

It is understandable that you need to know what your new labels will look like before revising your website. This would be acceptable to revise the website after the January 3, 2011 deadline. You are not expected to

accomplish everything by January 3<sup>rd</sup>, but at least to have a plan for how your company will come into compliance and reasons why you would need additional time. I look forward to hearing from you on January 3<sup>rd</sup>

Sincerely,

Renee Mann

From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Thursday, December 23, 2010 9:28 PM
To: Mann, Renee
Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11

Hello Renee,

Regarding your request to provide the information as listed, #3 requests that the labels be revised on our website to be compliant. I would like to request that we are given additional time to make the website graphic changes once you have received our revised labels and graphics on Jan. 3rd 2011 and have returned with an "approved" status as to each one. The reason for this is that it will take some IT work to replace all of the graphics files on the website and we would like to be sure that the revised graphics are indeed acceptable and approved by NOP prior to posting all of them online. Would this be acceptable?

Sincerely,

Dr. Bartell

------ Original Message ------Subject: RE: SereniGy, NOP Complaint Case Number NOPC-005-11 From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Wed, December 08, 2010 10:56 am To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

I made a mistake in my previous message. The deadline for submitting the below requested information is January 3, 2011, not January 1, 2010.

Sincerely,

Renee Mann

From: Mann, Renee Sent: Wednesday, December 08, 2010 12:16 PM To: <u>drbartell@serenigy.com</u> Subject: SereniGy, NOP Complaint Case Number NOPC-005-11 Dear Dr. Bartell,

It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code of Federal Regulations, 7 CFR §205, National Organic Program.

Specifically, the complaint alleges that the Gourmet Black Coffee and Gourmet Latte are not certified as organic. Additionally, I have identified several other products on your website that may have labeling violations, which we discussed.

Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create labels that are compliant with the regulations. Pay specific attention to §205.100 *What has to be certified*, §205.101 *Exemptions and exclusions from certification* and Subpart D-Labels, Labeling, and Market Information.

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?

c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7
If the above link does not work, you can also navigate to the regulations through the NOP
website's Resource Center: <a href="http://www.ams.usda.gov/NOPResourceCenterRegulations">http://www.ams.usda.gov/NOPResourceCenterRegulations</a>
In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010:

Submit the current product labels, including information and display panels, for the following products:

Gourmet Black Coffee Gourmet Latte Gourmet Mocha Gourmet Hot Chocolate Gourmet Chai Tea Organic Green Tea Gourmet Organic Rooibos Tea SG Ganoderma Essential SG Time Capsule SG Slim SereniGy Fruit & Veggie Power Plus.

Submit revised labels for the abovementioned products that are compliant with the NOP regulations.

Revise the abovementioned labels on the website, and ensure that references to "organic" products or ingredients are in compliance with the NOP regulations.

Identify the manufacturer of the abovementioned products that processes and labels the finished product.

Submit the organic certificate of the ganoderma that is used in the SereniGy products.

Provide a proof of purchase of the ganoderma (by the manufacturer identified in number 3 above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4)(iii) records must be maintained by the exempt handling operation).

Confirm that the Nutraceutical *SG Lightning* does not claim "organic" on its label. You could meet this requirement by submitting the current product label.

If you have any questions, please feel free to contact me at (202) 205-5213 or

renee.mann@ams.usda.gov. Also, please note that I will be on vacation from December 20<sup>th</sup>

through December 25<sup>th</sup>. If I am unavailable, you may contact a representative of the NOP through the main NOP phone line at (202)720-3252.

Sincerely,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <a href="http://bit.ly/NOPOrganicInsiderRegistration">http://bit.ly/NOPOrganicInsiderRegistration</a>
From:	KIDD, CHIP W OGC
To:	Michael, Matthew - AMS
Cc:	<u>Mann, Renee - AMS</u>
Subject:	RE: SereniGy
Date:	Tuesday, March 19, 2013 7:47:14 AM

Thank you.

Buren "Chip" Kidd Attorney Marketing, Regulatory, and Food Safety Programs Office of the General Counsel U.S. Department of Agriculture Telephone: (202) 720-2633 Fax: (202) 690-4299 Email: <u>Chip.Kidd@ogc.usda.gov</u>

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From: Michael, Matthew - AMS Sent: Monday, March 18, 2013 2:09 PM To: KIDD, CHIP W. - OGC Cc: Mann, Renee - AMS Subject: SereniGy

Hi Chip:

I put in your mailbox (b)(5)(1),(b)(5)(2) SereniGy Global. in regard to

Let me or Renee know if you have any questions or need any more information.

Thanks.

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov

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From:	drbartell@serenigy.com
To:	Mann, Renee - AMS
Cc:	Suzy Guillory
Subject:	RE: Settlement Agreement, NOPC-005-11
Date:	Tuesday, March 20, 2012 1:30:16 PM

Hello Renee,

Thank you for the help on our compliance. The two items the NOP has found that indicate we are not in compliance was a shock to me. I am currently in communications with my manufacturer and they have communicated with QAI regarding the Slim product label for clarity on this as we had understood we were compliant on all of our products. Also with the Chai Tea I am researching and will have a response in the next few days.

Thank you,

Dr. Bartell

cc Ms. Suzy Guillory

------ Original Message ------Subject: Settlement Agreement, NOPC-005-11 From: "Mann, Renee - AMS" <<u>Renee.Mann@ams.usda.gov</u>> Date: Thu, March 15, 2012 7:18 am To: "Bartell (<u>drbartell@serenigy.com</u>)" <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell:

Please see the attached letter and settlement agreement in response to your letter dated February 6, 2012.

Sincerely,

Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Stay informed by joining the National Organic Program mailing list.

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From:Allen, CareyTo:Mann, Renee - AMSSubject:RE: Unauthorized use of QAI sealDate:Friday, February 22, 2013 8:46:53 AMAttachments:SereniGy Global, Inc. 011111 C&D Letter.pdf

### Hi Renee,

Here is the letter that Maria sent on Jan 11, 2011. Is there anything else I can help with on this?

# Carey Allen

Quality Specialist NSF International Quality Assurance International (QAI) 734 214 6261 callen@nsf.org

From: Mann, Renee - AMS [mailto:Renee.Mann@ams.usda.gov] Sent: Thursday, February 21, 2013 5:13 PM To: Allen, Carey Subject: FW: Unauthorized use of QAI seal

Hi Carey:

I hope you can help me located a letter that QAI sent to SereniGy. If you look at the email chain

below, you will see the original email the accompanied the letter, which was sent on January 11<sup>th</sup> by Maria DeVincenzo. Do you still have this letter? I am still working on an open investigation against SereniGy (NOPC-005-11) and this letter would help that investigation.

Please let me know if you have any questions.

Thank you,

Ms. Renee Mann Compliance Specialist USDA National Organic Program +1 (202) 205-5213

From: DeVincenzo, Maria [mailto:Maria@qai-inc.com] Sent: Monday, January 17, 2011 7:11 PM To: Mann, Renee Subject: FW: Unauthorized use of QAI seal

# Hi Renee,

Below is the response I received from Serenigy regarding the cease and desist letter I sent. He seems a little confused regarding being able to label his product organic and the use of the USDA seal. As he states that he is waiting for your approval.

I also contacted <sup>(b)(4)</sup> to make sure that they were not packaging and labeling this product. I received the attached emails from <sup>(b)(4)</sup> they also seem a little confused about the certification process. We will be contacting them tomorrow to see who there copacker is and if the facility is certified.

Regards.

Maria DeVincenzo Quality Specialist Quality Assurance International 9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 USA (858) 200-9727 Phone (734) 827-6177 Fax www.gai-inc.com



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From: drbartell@serenigy.com [mailto:drbartell@serenigy.com] Sent: Thursday, January 13, 2011 3:01 PM To: DeVincenzo, Maria Subject: RE: Unauthorized use of QAI seal

Hello Maria,

Our company SereniGy Global Inc. is a brand new company as of last year and has just begun with these new products. Thank you for the information regarding the labeling of our four products listed (Time capsules, Essential capsules, Fruit & Veggie Capsules, and Slim tablets) which we included the QAI logo. We have learned there was a misunderstanding and lack of information in the process of our design and wording of these labels that we applied. The reason we used the QAI logo is that the raw ingredient supplier of the Organic Ganoderma herb used in each of these four SereniGy products (19(4) is certified by you and we believed we had the liberty to therefore use the logo on our labels as we are using this QAI certified organic ingredient.

Last month we were contacted by Renee Mann a Compliance Specialist with the USDA National Organic Program letting us know that these labels were believed to not be in compliance with the USDA organic labeling regulations. Upon review of the regulations we have recognized the errors of the labeling and have since changed these labels to reflect and be in compliant with the NOP. These new labels are currently being reviewed for approval and we are waiting for their approval at this time.

We wish to clarify this use of the logo with you so that we may correct our labels and be in complete compliance with your certification regarding our products and their labeling. I request that once the revised labels are approved by NOP, that we send you the approved labels for your review and approval for using the QAI logo on these products. Our intention

is to fully comply with your certification requirements of which we will possibly need some guidance and review. Thank you for your consideration in this matter and please let me know if this process to correct our product labels is acceptable

Sincerely,

Dr. Kent Bartell SereniGy Global Inc. VP product R & D. 918-724-4974

The information in this email is considered proprietary and confidential.

------ Original Message ------Subject: Unauthorized use of QAI seal From: "DeVincenzo, Maria" <<u>Maria@qai-inc.com</u>> Date: Tue, January 11, 2011 3:50 pm To: <<u>drbartell@serenigy.com</u>> Cc: "NOPACAAdverseActions" <<u>NOPACAAdverseActions@ams.usda.gov</u>>

Dr Bartell,

Please see the attached correspondence regarding the unauthorized use of the QAI seal.

Maria DeVincenzo Quality Specialist Quality Assurance International 9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 USA (858) 200-9727 Phone (734) 827-6177 Fax www.qai-inc.com

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error, please immediately notify the sender without reading it and do not take any action based on its contents or otherwise copy or disclose it to anyone. Any opinions or views expressed in this transmission are solely of the author and do not necessarily represent those of NSF International or its affiliates.

### Hi Maria,

Thank you for forwarding all of this correspondence to me. We do seem to have several confused operators here! Please let me know what comes of <sup>(b)(4)</sup> communication with you regarding the packaging and certification of Serenigy products. I should be able to review the documents submitted in the next few days and I will be contacting Dr. Bartell soon. I will keep you informed of my progress so that we both understand what is happening here.

Regarding the label "approval," Serenigy is working with the NOP to get an "approval" of their labels, for a lack of a better term, so that I can close the complaint against their company. Basically, I need Dr. Bartell to submit labels that are no longer in violation of the NOP regulations. This will most likely mean that he will submit labels to me where he has removed the QAI logo, the USDA seal, and reference to "organic." Unfortunately, he has revised his labels once and his attempt was not acceptable because he still doesn't understand that he can't use the QAI logo and that he is far from having a "certified" product because his product is probably not packaged at a certified facility. We haven't gotten very far in our communication because I've only asked him for information once and haven't yet responded to him while I was waiting to see what QAI determined regarding several products' certification.

Not to confuse this further, but he does have two teas (green tea and rooibos) that are certified and packaged at a facility in <sup>(b)(4)</sup> Those tea products are certified by the Nevada Department of Agriculture. So, he seems to have contracted out work on his various product lines to various operations and he doesn't understand much about the NOP regulations.

Kind Regards,

Renee

From: DeVincenzo, Maria [mailto:Maria@qai-inc.com] Sent: Monday, January 17, 2011 7:11 PM To: Mann, Renee Subject: FW: Unauthorized use of QAI seal

# Hi Renee,

Below is the response I received from Serenigy regarding the cease and desist letter I sent. He seems a little confused regarding being able to label his product organic and the use of the USDA seal. As he states that he is waiting for your approval.

I also contacted <sup>(b)(4)</sup> to make sure that they were not packaging and labeling this product. I received the attached emails from <sup>(b)(4)</sup> they also

seem a little confused about the certification process. We will be contacting them tomorrow to see who there copacker is and if the facility is certified.

Regards.

Maria DeVincenzo Quality Specialist Quality Assurance International 9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 USA (858) 200-9727 Phone (734) 827-6177 Fax www.gai-inc.com

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From: drbartell@serenigy.com [mailto:drbartell@serenigy.com]
Sent: Thursday, January 13, 2011 3:01 PM
To: DeVincenzo, Maria
Subject: RE: Unauthorized use of QAI seal

Hello Maria,

Our company SereniGy Global Inc. is a brand new company as of last year and has just begun with these new products. Thank you for the information regarding the labeling of our four products listed (Time capsules, Essential capsules, Fruit & Veggie Capsules, and Slim tablets) which we included the QAI logo. We have learned there was a misunderstanding and lack of information in the process of our design and wording of these labels that we applied. The reason we used the QAI logo is that the raw ingredient supplier of the Organic Ganoderma herb used in each of these four SereniGy products <sup>(b)(4)</sup> is certified by you and we believed we had the liberty to therefore use the logo on our labels as we are using this QAI certified organic ingredient.

Last month we were contacted by Renee Mann a Compliance Specialist with the USDA National Organic Program letting us know that these labels were believed to not be in compliance with the USDA organic labeling regulations. Upon review of the regulations we have recognized the errors of the labeling and have since changed these labels to reflect and be in compliant with the NOP. These new labels are currently being reviewed for approval and we are waiting for their approval at this time.

We wish to clarify this use of the logo with you so that we may correct our labels and be in complete compliance with your certification regarding our products and their labeling. I request that once the revised labels are approved by NOP, that we send you the approved labels for your review and approval for using the QAI logo on these products. Our intention is to fully comply with your certification requirements of which we will possibly need some guidance and review. Thank you for your consideration in this matter and please let me

know if this process to correct our product labels is acceptable

Sincerely,

Dr. Kent Bartell SereniGy Global Inc. VP product R & D. 918-724-4974

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Dr Bartell,

Please see the attached correspondence regarding the unauthorized use of the QAI seal.

Maria DeVincenzo Quality Specialist Quality Assurance International 9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 USA (858) 200-9727 Phone (734) 827-6177 Fax www.qai-inc.com

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#### Hi Matthew,

Your proposed letter looks good. Thanks for responding to Serenigy's lawyer.

Kind Regards, Renee

From: Michael, Matthew - AMS Sent: Tuesday, April 17, 2012 2:46 PM To: Mann, Renee - AMS Subject: RE: USDA NOP compliance Importance: High

# What do you think?

Thanks.

-----

Hi Ms. Allen:

Thank you for your email.

In regard to the regulations in §205.662 et seq., those requirements govern the noncompliance notification procedure between a certifying agent or a State organic program and a certified operator. Our March 15, 2012, letter and settlement offer to SereniGy Global Inc. (SereniGy) is not subject to these regulations, as the National Organic Program (NOP) is neither a certifying agent nor State organic program and SereniGy is not a certified operator. The March 15, 2012, correspondence instead represents an offer to settle informally the matter of Serenigy's previously cited violations of the NOP regulations, as well as its continuing violations of the regulations at 7 CFR parts §205.100(a), 205.102 and §205.300(a).

Note that in this recent settlement offer, in acknowledgment of SereniGy's attempts to come into compliance with the regulations, the NOP reduced the amount of the proposed civil penalty from the amount offered in the January 10, 2012, settlement proposal (from \$12,000 to \$4,000). Note also that this proposed settlement is an alternative to an administrative proceeding, the outcome of which could be an administrative law judge assessing civil penalties of up to \$11,000 per violation of the NOP regulations. The settlement agreement and civil penalty are still offered as stated in the letter of March 15, 2012. If you agree to the terms of the settlement agreement, please sign the original and return it to the address noted in the letter immediately, along with a certified check or money order made payable to the "Treasurer of the United States."

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov

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From: Julia Allen [mailto:juliadallen@yahoo.com] Sent: Thursday, April 05, 2012 12:22 PM To: Mann, Renee - AMS; Michael, Matthew - AMS Cc: Kent Bartell Subject: USDA NOP compliance

Julia D. Allen Allen Law Office 3400 East 33rd Street Tulsa, Oklahoma 74135 (918) 585-5500 (918) 392-0510 facsimile

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Hi Ms. Allen:

Thank you for your email.

In regard to the regulations in §205.662 et seq., those requirements govern the noncompliance notification procedure between a certifying agent or a State organic program and a certified operator. Our March 15, 2012, letter and settlement offer to SereniGy Global Inc. (SereniGy) is not subject to these regulations, as the National Organic Program (NOP) is neither a certifying agent nor State organic program and SereniGy is not a certified operator. The March 15, 2012, correspondence instead represents an offer to settle informally the matter of Serenigy's previously cited violations of the NOP regulations, as well as its continuing violations of the regulations at 7 CFR parts §205.100(a), 205.102 and §205.300(a).

Note that in this recent settlement offer, in acknowledgment of SereniGy's attempts to come into compliance with the regulations, the NOP reduced the amount of the proposed civil penalty from the amount offered in the January 10, 2012, settlement proposal (from \$12,000 to \$4,000). Note also that this proposed settlement is an alternative to an administrative proceeding, the outcome of which could be an administrative law judge assessing civil penalties of up to \$11,000 per violation of the NOP regulations. The settlement agreement and civil penalty are still offered as stated in the letter of March 15, 2012. If you agree to the terms of the settlement agreement, please sign the original and return it to the address noted in the letter immediately, along with a certified check or money order made payable to the "Treasurer of the United States."

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

Sent: Thursday, April 05, 2012 12:22 PM To: Mann, Renee - AMS; Michael, Matthew - AMS Cc: Kent Bartell Subject: USDA NOP compliance

Julia D. Allen Allen Law Office 3400 East 33rd Street Tulsa, Oklahoma 74135 (918) 585-5500 (918) 392-0510 facsimile

This message contains confidential information that is legally privileged. If you are not the intended recipient you cannot disclose, copy, or distribute this message.

Hello Maria,

Please re-send the emails that you tried to send to me earlier in the week regarding Serenigy My IT person informed me that I should now receive your emails if you send them again.

Also, do you know if <sup>(b)(4)</sup> was knowingly making those labels for Serenigy? That is what Serenigy claimed in a letter to me, which would be a noncompliance on <sup>(b)(4)</sup> part for not getting the labels approved through QAI first. If you haven't checked into that, please do so. In order to fully investigate the complaint, I need documentation that the certifier did its due diligence to determine that its certified operation was not at fault.

Thanks,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <u>http://bit.ly/NOPOrganicInsiderRegistration</u>

### Dear Dr. Bartell,

Thank you for submitting your response on January 3, 2011 to the NOP regarding your various product labels that identify organic ingredients.

I have been in communication with Quality Assurance International (QAI) regarding the Time, Essential, and Slim labels. QAI issued a cease and desist notification to you because your labels cannot carry the QAI logo if your final product is not certified by QAI. To clarify, in order to display the USDA seal, the words "certified organic" or the QAI logo, the entire product would need to be certified as organic by QAI. Because only the ganoderma in the product is certified and the entire product is not certified, you cannot use the "certified organic" label claim, USDA seal or QAI logo. The finished product is certified only by being produced in an organic certified facility by a company that carries certification AND if the product labels have been reviewed and approved by the certification agency, such as QAI.

Please revise the supplement labels that contain references to QAI by removing the QAI logo and any reference to QAI. You can still obtain certification for these products in the future, but currently because the products are not certified, the labels must not display the QAI logo. To obtain certification, your supplier or you may work directly with a certifier, such as QAI, to obtain approval for the labels.

In relation to the Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate and Gourmet Chai Tea, the term "100% Certified" on the principal display panel (front panel) appears to reference the organic certification of the ganoderma ingredient. This is a violation of 7 CFR §205.100 and §205.305(a) because the claim could mislead customers to think that the entire coffee or tea product is 100% certified. Only products that are certified may be identified or represented as organic on the principal display panel. Please revise these labels again to remove the term "certified" and submit proofs to the NOP for review.

Thank you for providing the proof of purchase of the <sup>(b)(4)</sup> ganoderma product. In relation to your other manufacturers, please identify from what company the ganoderma is purchased that is subsequently used by <sup>(b)(4)</sup> and <sup>(b)(4)</sup> carries to manufacture the Serenigy products. QAI confirmed that <sup>(b)(4)</sup> carries certification for its ganoderma product but I need to confirm that the ganoderma going into all of your products is certified. If there is another source besides <sup>(b)(4)</sup> please provide the certificates for the additional ganoderma products and the proofs of purchase.

Please provide your response by February 18, 2011. If you have any questions, feel free to contact me at (202) 205-5213 or <u>renee.mann@ams.usda.gov</u>.

Sincerely,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <u>http://bit.ly/NOPOrganicInsiderRegistration</u>

Hello Renee,

Here is the revised Fruit & Veggie label.

Thank you,

Dr. Bartell

Please let me know when you get this. Thanks!

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at http://bit.ly/NOPOrganicInsiderRegistration

From:	Allen, Carey
To:	Mann, Renee - AMS
Subject:	SereniGy - Slim
Date:	Tuesday, March 13, 2012 3:44:50 PM
Attachments:	Slim product.msg
	(b)(4) <u>pdf</u>

#### Renee,

More information from (b)(4) regarding SereniGy. See below explanation of the tableter and the attached certificate. Additionally, the attached message from (b)(4) regarding the production trial. May I ask, did you obtain the Slim product from the SereniGy website?

## Carey Allen

Quality Specialist Quality Assurance International NSF International 734 214 6261 callen@nsf.org

From: Orr, Emily Sent: Tuesday, March 13, 2012 2:41 PM To: Allen, Carey Subject: RE: SereniGy - Slim

Carey,

Organic Certifiers certifies (b)(4) I was informed by(b)(4) that this company is changing their name to (b)(4) (b)(4) is the company that encapsulates and packs the mushroom products that (b)(4) grows, including for the SereniGy ID Mark.(b)(4) works directly with (b)(4) with the product packaging. I don't know who her contact at SereniGy is. I have attached (b)(4) last email to me regarding this matter.

*Emily Orr* <u>eorr@qai-inc.com</u> P: (858)200-9337 F: (734)827-7764

not necessarily represent those of NSF International or its affiliates.

From:	Michael, Matthew - AMS
То:	Ricci, Carrie; KIDD, CHIP W OGC; MARTIN, FRANK - OGC
Cc:	Mann, Renee - AMS
Subject:	SereniGy and complaints for hearing
Date:	Thursday, May 09, 2013 9:27:55 AM

Hi Carrie, Chip and Frank:

(b)(5)(1),(b)(5)(2)		

Let me know if you want to meet again. We appreciate OGC reviewing the SereniGy case and I know we'll figure something out.

Thanks.

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 <u>matthew.michael@ams.usda.gov</u>

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Hello Renee,

Here is the revised Black box.

Thank you,

Dr. Bartell



Hello Renee,

Here is the revised Chai Box.

Thank you,

Dr. Bartell







Ce prodult n'est pas conçu pour diagnostiquer, traiter, guérir ou prévenir une maladie. This product is not intended to diagnose, Este producto no pretende diagnosticar

NE PAS UTILISER SI LE SCEAU

DE SÉCURITÉ EST BRISÉ.

EVIDENT SEAL IS BROKEN.

DO NOT USE IF TAMPER

Lot No.: 080410-GE Best By: Apr. 2013

**NO UTILIZAR SI ES EVIDENTE** 

QUE EL SELLO ESTA ROTO.

treat, cure or prevent any disease.

Exclusively formulated and distributed by: Exclusivamente formulado y distribuido por: Préparé et distribué exclusivement par-

tratar, curar o prevenir ninguna enfermedad

201 South Biscayne Blvd., Suite #2800 SereniGy Global, Inc. Miami, FI 33131



# rganie Sanoderma 180 Capsules ~ 600 mg ea. GIOBA **Dietary Suppleme** with 100% Certified

NO UTILIZAR SI ES EVIDENTE QUE EL SELLO ESTA ROTO.

This product is not intended to diagnose, treat, cure or prevent any discase.

Ce produit n'est pas conçu pour diagnostiquar, traiter, guêntr ou prêvenir une maladie.

Este producto no pretende diagnosticar, tratar, curar o prevenir ninguna enfermedad.

Exclusively formulated and distributed by Propore et distribue exclusivement par. Exclusivemente formulado y distribuido por

201 South Biscayne Blvd., Suite# 2800 Miami, FI 33131 SereniGy Global, Inc.

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN.

NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ.



9191 Towne Centre Drive, Suite 510 San Diego, CA 92122 • USA 858-792-3531 • Fax: 858-792-8665 www.qai-inc.com

January 11, 2011

Dr. Kent Bartell VP of Product Research and Development SereniGy Global, Inc. 201 South Biscayne Blve. Suite #2800 Miami, FL 33131

Re: Unauthorized use the QAI Seal

Dear Dr. Bartell:

It has come to the attention of Quality Assurance International (QAI) that SereniGy Global, Inc. is using the QAI seal on your product labels stating that they are "Certified Organic by QAI" and thus implying that SereniGy Global, Inc. is certified by QAI, when in fact, your products are not certified by QAI.

You should appreciate that QAI, like any other trademark owners, must protect its valuable trademark rights. Unless we pursue unauthorized uses of our marks, the value of the marks will be impaired. We must therefore require that you remove the QAI seal from all product labels no later than January 25, 2011.

Should you choose not to remove the QAI seal from all your product labels we will have no choice but to consider the legal options available to us to protect our Registered Trademark.

If you have any questions I can be reached at 858-200-9727 or you can e-mail me at <u>maria@qai-inc.com</u>.



cc: Administrator USDA National Organic Program





Lot No.: 080410-GE Best By: Apr. 2013 DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN. NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ.

NO UTILIZAR SI ES EVIDENTE QUE EL SELLO ESTA ROTO. This product is not intended to diagnose, treat, cure or prevent any disease. Ce prodult n'est pas conçu pour diagnostiquer, traiter, guérir ou prévenir une maiadie. Este producto no pretende diagnosticar, tratar, curar o prevenir ninguna enfermedad.

Exclusively formulated and distributed by: Préparé et distribué exclusivement par: Exclusivemente formulado y distribuido por:

SereniGy Global, Inc. 201 South Biscayne Bivd., Suite #2800 Miaml, FI 33131







Miami, Fi 33131

From:	Mann, Renee
To:	maria@qai-inc.com
Subject:	Serenigy Global product line - email 2 of 2
Date:	Thursday, January 06, 2011 6:13:00 PM
Attachments:	Serenigy Essential Label - current.jpg
	Serenigy Fruit Veggie Label - current.jpg

Maria,

You should receive 4 files total: 2 in each email.

Thanks,

Renee



Sevenity Brurnet Black Coffie it make ushicis time of the fract coffee beast and blended with our proprietury Serenity Proprietary Blend ula of 100% Certifiel Bunderna extract 4 Acon



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Ingredientes: Café y Extracto de Ganoderma Orgánico

Directions: Empty 1 sachet into your favorite cup, fill with 8 ounces of

This Is My Coffee

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Seren

hot water, stir and enjoy!

Directions: Verser 1 sachet dans votre tasse préférée, ajouter 8 onces d'eau

chaude, remuer et savourer!

Coffee and Organic Ganoderma Extract Ingrédients: Café et Extrait de Ganoderma Organique

Ingredients:

# Nutrition Facts Valeur Nutritive

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with 100% Certified Ganoderma Extract

Screnity Proprietary Bl

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2.5g x 30 sachets Net Wt. 2.6 OZ (75g)

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Extrait de Ganoderma Certifié à 100% 2.5g x 30 sachets Poids Net 2.6 OZ (75g)

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NAU CAFÉ PRÉALABLEMENTA

Srevete O

MIAMI, FL 33131

EXCLUSIVELY DISTRIBUTED BY: DISTRIBUÉ EXCLUSIVEMENT PAR: DISTRIBUIDO EXCLUSIVAMENTE POR.

SERENIGY GLOBAL, INC. 201 SOUTH BISCAYNE BLVD. SUITE# 2800

en su taza favorita, agregue 8 onzas de agua caliente, revuelve y disfrutelo! Instrucciones: Coloque 1 bolsita

SERENIGY GLOBAL HOLDINGS, INC. 115B - 19705 FRASER HWY. LANGLEY, BC V3A 7E9

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Secondy Proprietary Blad

PRE-BREWED COFFEE BEVERAGE with 100% Certified Ganoderma Extract 34g x 15 sachets Net Wt.18 0Z (510g)

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Here is the revised Coco / Hot Chocolate Box.

Thank you,

I hope you have received the email from<sup>(b)(4)</sup> today with the newest labels that are being submitted to QAI for approval. I will also be sending you the other 5 corrected beverage boxes tomorrow Friday 02/18/2011 as soon as I get them back from our graphics design department.

Thank you,

Here is the revised Latte Box.

Thank you,

Here is the revised Mocha Box.

Thank you,

December 5, 2010

Jay Noland Basil Childress Jaime Lyn Marquez SereniGy Global Inc. 201 S. Biscayne Blvd. Ste 2800 Miami, FL 33131

Re: NOP Complaint Case Number NOPC-005-11

Dear Mr. Noland, Mr. Childress, and Ms. Marquez:

The U.S. Department of Agriculture (USDA) National Organic Program (NOP) has received a complaint alleging that your company markets its products with the term "100% certified organic" without certification of the final product, which is a violation of the NOP regulations. Specifically, the following possible violations have been identified:

- 1. Claims of "with 100% Certified Organic Ganoderma Extract" on the front panels of SereniGy's Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate, and Gourmet Chai Tea
- Claims of "100% Certified Organic Green Tea" and "100% Certified Organic Rooibos Tea" on the SereniGy Global Gourmet Organic Green Tea and SereniGy Global Gourmet Organic Rooibos Tea, respectively, in addition to claims of "with 100% Certified Organic Ganoderma"
- Claims of "100% Certified Organic Ganoderma" used on the Neutraceuticals products: SG Ganoderma Essential, SG Time Capsule, SG Slim, SereniGy Fruit & Veggie Power Plus, SG Lightning
- 4. Statements of "100% Certified Organic" in reference to various products that are not certified on the SereniGy website.

The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a USDA accredited certifying agent. Also, all such agricultural commodities must comply with the Code of Federal Regulations: 7 CFR Part 205, National Organic Program.

Please be advised that failure to <u>cease and desist</u> use of the term "organic" and "certified organic" on the SereniGy product labels when SereniGy does not have organic certification and failure to comply with the NOP regulations may result in a civil penalty of \$11,000 per

violation.

I previously sent two letters to your office on November 15 and December 1, from which I have not received a response. Please contact me immediately upon receipt of this letter to discuss the complaint. If your products are certified organic, then your products may be in compliance with the organic regulations. However, to confirm this, I need to know the name of your organic certifier. Please contact me at (202) 205-5213 or <u>renee.mann@ams.usda.gov</u>. Thank you for your attention to this matter.

Sincerely,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

1400 Independence Ave. SW Room 2646-S, Mail Stop 0268 Washington, DC 20250



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From:	drbartell@serenigy.com	
To:	Mann, Renee - AMS	
Cc:	Suzy Guillory; Morgan Tharpe	
Subject:	SereniGy Response regarding the NOP Letter	
Date:	Monday, March 26, 2012 1:25:32 PM	
Attachments:	(b)(4)	

I have had the opportunity to speak with our CEO on this matter and research the two items that NOP has claimed that we were not compliant on regarding labeling of our products. These were the Slim QAI logo and the Chai Tea "100% Certified Rooibos" phrase. I would like to provide an explanation in hopes that consideration may be made to accept our compliance in this matter as we have worked diligently to comply with all of the USDA NOP requirements as given and have been advised that we should not be fined for non-compliance. Thank you for consideration in this matter...

I was under the belief that all the product labels and boxes that I sent to you were compliant including the Chai Tea and the Slim Tablets. I had send both of these labels to you in pdf form last year on 2/18/2011 for your review and had not received any notice back that any of these had non-compliant information on them. After getting your letter last week I quickly contacted (b)(4) (b)(4) said last year in the fall they had been working with their tableter for about 3 months on finalizing an organic tablet excipient formula that would work to make the Slim tablets hard enough. (b)(4) who takes care of processing the purchase orders thought that since (b) had submitted Time and Ganoderma Essential labels for approval as well as the Slim label for proof that we were working to be compliant, that approval with QAI was across the board for all 3 of these labels. Also around the same time she said she had received QAI approval for the Slim Powder, which also added to the internal confusion at (b)(4).

At the same time that (b)(4) released the 'trial' run of Slim bottles to us (which was unknown to (b)(4)), she was working with their tableter and their organic certifying agency to get their approval for the completed Slim tablet. They just finally got the QAI approval from QAI and so the labels are clear to use. We request that you confirm with QAI and also see the attached document that lists the Slim product towards the bottom along with the Essential and Time capsules to use the QAI logo and release us from the fine associated with this product.

Regarding the Chai Tea, please see your response to our beverages section that you sent me on January 27th, 2011...

------ Original Message ------Subject: Response regarding organic labeling From: "Mann, Renee" <<u>Renee.Mann@ams.usda.gov</u>> Date: Thu, January 27, 2011 12:12 pm To: <<u>drbartell@serenigy.com</u>>

Dear Dr. Bartell,

Thank you for submitting your response on January 3, 2011 to the NOP regarding your various product labels that identify organic ingredients.

In relation to the Gourmet Black Coffee, Gourmet Latte, Gourmet Mocha, Gourmet Hot Chocolate and Gourmet Chai Tea, the term "100% Certified" on the principal display panel (front panel) appears to reference the organic certification of the ganoderma ingredient. This is a violation of 7 CFR §205.100 and §205.305(a) because the claim could mislead customers to think that the entire coffee or tea product is

100% certified. Only products that are certified may be identified or represented as organic on the principal display panel. Please revise these labels again to remove the term "certified" and submit proofs to the NOP for review.

Renee, as per your instructions below we removed the term '100% certified" from all of the "principal display panel (front panel) of the boxes. It was never indicated that this term could not be listed on nonprincipal panels of the box. Regarding the Chai Tea, the "100% certified Rooibos" is not listed on the principal display panel (front face), but in the paragraph on the top of the box. I sent you a copy of this same box in February 2011. Our Rooibos Tea powder ingredient in this product is in fact a USDA certified organic herb and so the phrase "100% certified Rooibos" is accurate and does not give an indication that the entire product is certified organic. We followed the NOP instructions exactly to be compliant on all of our products and believe we should not be fined and the SereniGy NOP case closed.

Thank you for your continued help and we await your reply,

Sincerely,

Dr. Kent Bartell

cc Ms. Suzy Guillory V. P. cc Mr. Morgan Tharpe V.P.

Dear Dr. Bartell:

Thank you for your correspondence dated March 26, 2012. We understand your position regarding the noncompliances listed in my March 15, 2012, letter to you. The settlement agreement and civil penalty are still offered as stated in that letter. If you agree to the terms of the settlement agreement, please sign the original and return it to the address noted in the letter by March 31, 2012, along with a certified check or money order made payable to the "Treasurer of the United States."

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov

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Lot No.: 080410-SGS Best By: Apr. 2013 DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN. NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ. NO UTILIZAR SI ES EVIDENTE QUE EL SELLO ESTA ROTO. This product is not intended to diagnose treat, cure or prevent any disease. Ce produit n'est pas conçu pour diagnostique traiter, guérir ou prévenir une maladie.

Este producto no pretende diagnosticar, tratar, curar o prevenir ninguna enfermeda

Exclusively formulated and distributed by: Préparé et distribué exclusivement par: Exclusivemente formulado y distribuido por:

SereniGy Global, Inc. 201 South Biscayne Blvd., Suite #2800 Miami, FI 33131

# Lot No.1 201011-565 Best By: Oct. 2014

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Best by: Oct. 2014 DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN IF AS UTILISER SILE SCEAU DE SCOURTE EST BRISE. NO UTILIZAR SI ES EVIDENTE OUE EL SELLO ESTA ROTO. Inveduct is not intended to diagnose medicate or prevent any disease. Inveduct is not intended to diagnose medicate or prevent une malactic tas positic ou prevente une malactic tas positic ou prevente une malactic tas positic ou prevente une malactic

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# Screnity Stime Bline

March 1

Hade with Organic Ganoderma 90 Tablets ~ 750 mg ea.



Dear Dr. Bartell,

It was a pleasure talking with you on Monday. As discussed during our conversation, the National Organic Program (NOP) received a complaint about your company. The complaint alleges that your company advertises some of its products as organic without certification, which is a violation of the NOP regulations. The NOP implements the Organic Foods Production Act of 1990 that requires that all agricultural commodities sold, labeled or represented as organic be certified by a United States USDA accredited certifying agent and must comply with the Code of Federal Regulations, 7 CFR §205, National Organic Program.

Specifically, the complaint alleges that the Gourmet Black Coffee and Gourmet Latte are not certified as organic. Additionally, I have identified several other products on your website that may have labeling violations, which we discussed.

Thank you for confirming which products are organic and for providing me with the information about the certifier of the green tea and rooibos tea. From our discussion, I understand that the ganoderma is certified organic, but the coffee is not certified organic. Also, I understand that the nutraceutical products, coffee products, and the chai tea are not certified. Please review the NOP regulations below so that you may create labels that are compliant with the regulations. Pay specific attention to \$205.100 *What has to be certified*, \$205.101 *Exemptions and exclusions from certification* and Subpart D-Labels, Labeling, and Market Information.

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?

c=ecfr&sid=0fdd0b10cc7b2591fe145f95c95da42b&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7 If the above link does not work, you can also navigate to the regulations through the NOP website's Resource Center: <u>http://www.ams.usda.gov/NOPResourceCenterRegulations</u>

In order to respond to the complaint, the NOP requests that you provide us the following information by January 1, 2010:

- 1. Submit the current product labels, including information and display panels, for the following products:
  - a. Gourmet Black Coffee
  - b. Gourmet Latte
  - c. Gourmet Mocha
  - d. Gourmet Hot Chocolate
  - e. Gourmet Chai Tea
  - f. Organic Green Tea
  - g. Gourmet Organic Rooibos Tea
  - h. SG Ganoderma Essential
  - i. SG Time Capsule
  - j. SG Slim
  - k. SereniGy Fruit & Veggie Power Plus.
- 2. Submit revised labels for the abovementioned products that are compliant with the NOP regulations.
- 3. Revise the abovementioned labels on the website, and ensure that references to "organic" products or ingredients are in compliance with the NOP regulations.
- 4. Identify the manufacturer of the abovementioned products that processes and labels the finished product.
- 5. Submit the organic certificate of the ganoderma that is used in the SereniGy products.
- 6. Provide a proof of purchase of the ganoderma (by the manufacturer identified in number 3

above) showing the purchase of ganoderma from a certified operation (per §205.101(a)(4) (iii) records must be maintained by the exempt handling operation).

7. Confirm that the Nutraceutical *SG Lightning* does not claim "organic" on its label. You could meet this requirement by submitting the current product label.

If you have any questions, please feel free to contact me at (202) 205-5213 or renee.mann@ams.usda.gov. Also, please note that I will be on vacation from December 20<sup>th</sup> through December 25<sup>th</sup>. If I am unavailable, you may contact a representative of the NOP through the main NOP phone line at (202)720-3252.

Sincerely,

Renee Mann Compliance Specialist USDA National Organic Program (202)205-5213 office (202)205-7808 fax

Join the NOP mailing list at <u>http://bit.ly/NOPOrganicInsiderRegistration</u>

	(b)(6),(b)(7)(c),(b)(7)(d)
From:	
To:	NOPCompliance
Subject:	Serenigy
Date:	Thursday, October 14, 2010 8:30:04 PM

Dear Sir/Madam

I will appreciate if you could check if the products sold by Serenigy is organic as claimed by the company.

www.serenigy.com

and their products: http://www.serenigy.com/pages.aspx?id=39 http://www.serenigy.com/pages.aspx?id=40

We came across the products and did not find either a manufacturer or certification organization on the packaging eventhough it says it is 100% certified organic.

We would appreciate if you could check on the company and its product to ensure that we are getting what it claims it is. Thank you.



Hi Chip:

l put in your mailbox (b)(5)(1),(b)(5)(2) SereniGy Global. in regard to

Let me or Renee know if you have any questions or need any more information.

Thanks.

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov

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From:	Mann, Renee - AMS		
To:	Bartell (drbartell@serenigy.com)		
Subject:	Settlement Agreement, NOPC-005-11		
Date:	Thursday, March 15, 2012 10:18:00 AM		
Attachments:	2012-03-15 Settlement Letter.pdf		
	2012-03-15 Settlement Agreement revised.pdf		

Dear Dr. Bartell:

Please see the attached letter and settlement agreement in response to your letter dated February 6, 2012.

Sincerely,

Renee Mann Compliance Specialist, Compliance & Enforcement Division National Organic Program (202) 205-5213

Stay informed by joining the National Organic Program mailing list.



90 Tablets ~ 750 mg ea.

Lot No.: 080410-565 Best By: Apr. 2013 DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ.

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Este producto no pretende diagnosticar, tratar, curar o prevenir ninguna enfermeda

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SereniCy Global, Inc. 201 South Biscoyne Blvd., Suite #2800 Mami, Pt 33131 Certified Organic by OAI 

Serving Size 1 tablet

Amount Fex Serving
\* Daily Value

Certified Organic Genoderma Lucidum
\* Daily Value

<td

9 Tablets ~ 750 mg ea.

Lot No.: 080410-SGS Best By: Apr. 2013 DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN. NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ.

NO UTILIZAR SI ES EVIDENTE QUE EL SELLO ESTA ROTO. This product is not intended to diagnose treat, cure or prevent any disease. Ce produit n'est pas conçu pour diagnostiquer, traiter, guérir ou prévenir une maladie.

Este producto no pretende diagnosticar, tratar, curar o prevenir ninguna enfermeda

Exclusively formulated and distributed by: Próparé et distribué exclusivement par: Exclusivemente formulado y distribuido por:

SereniGy Global, Inc. 201 South Biscayne Blvd., Suite #2800 Miami, FI 33131

From:	(b)(4)
То:	<u>Orr, Emily</u>
Subject:	Slim product
Date:	Monday, March 12, 2012 1:30:07 PM

### Hi Emily,

I know that Carey called me last week regarding more info on the Slim product. I was so busy the day she called and then lost her phone number and went home sick on Friday. I virtually have no voice today which makes it impossible for phone communication! UGH!!!

So, can you forward her this email as I don't have her address?

We will be receiving the trial bottles of Slim back. It isn't even our policy to provide the customer with trial runs, so I don't know how that happened.

We are getting the finished/tableted product approved with our tableter's certifier. Last week they needed a couple minor things clarified which I think were provided to them on Friday. So I expect them to have their approval complete soon (I am hoping today!). I will submit all of the necessary paperwork to Emily once I have it from out tableter.

We also have the customer's powder blend at our tableter so once we get final approval from QAI our customer wants us to go into production.

## Thanks,



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Made with Organic Ganoderma 60 Capsules ~ 500 mg ea. Herbal Supplement GAN ELECTRON DE LE COMPANY

NE PAS UTILISER SI LE SCEAU De sécurité est brise. NO UTILIZAR SI ES EVIDENTE QUE EL SELLO ESTA ROTO.

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN.

Lot No.: 270110-TC Best By: Feb. 2013 This product is not intended to diagnose,

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Exclusively formulated and distributed by: Préparé et distribué exclusivement par:

Exclusivamente formulado y distribuido por. SereniGy Global, Inc.

201 South Biscayne Blvd., Suite #2800 Miami, Fi 33131 Certified Organic by QAI





From: To: Subject: Date:

# UPS Quantum View

Mann, Renee - AMS UPS Delivery Notification, Tracking Number Friday, January 13, 2012 1:36:32 PM



Discover more about UPS:	***Do not reply to this AMS/NOP will not rec	e-mail. UPS and USDA ceive your reply.
Visit www.ups.com Sign Up For Additional E-Mail From UPS	At the request of USDA AMS/NOP, this notice is to confirm that the following shipment has been delivered. Important Delivery Information	
<u>Read Compass</u> <u>Online</u>		
/ly Choice	Tracking Number: Delivery Date / Time:	(b) (4) 13-January-2012 / 12:07 PM
	Delivery Location: RECEPTION Signed by: <sup>(b) (6)</sup> Shipment Detail	
	Ship To: Dr. Bartell SereniGy 121 S 2ND ST JENKS OK 74037 US	
	Number of Package	
	UPS Service: Weight:	
	Reference Number Reference Number	

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Privacy Notice Contact UPS From:Julia AllenTo:Mann, Renee - AMS; Michael, Matthew - AMSCc:Kent BartellSubject:USDA NOP complianceDate:Thursday, April 05, 2012 12:22:10 PMAttachments:040512 letter to USDA.pdf

Julia D. Allen Allen Law Office 3400 East 33rd Street Tulsa, Oklahoma 74135 (918) 585-5500 (918) 392-0510 facsimile

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1400 Independence Avenue S.W. Room 2648-S, STOP 0268 Washington D.C. 20250-0268

# **Check Transmittal Memo**

- To: Lavern Harris Resource Management Branch Compliance & Analysis Agricultural Marketing Service
- From: Tammie Wilburn Compliance and Enforcement National Organic Program Agricultural Marketing Service
- **Date:** July 16, 2013
- **Re:** The Sixty NOPC-081-13 Settlement Agreement Payment

Enclosed is a <sup>(b)(4)</sup> check (<sup>b)(4)</sup>) from Kevin Edelman's <sup>(b)(4)</sup> in the amount of \$1,000.00, as payment of a Settlement Agreement between The Sixty and the USDA National Organic Program. This payment satisfies the Settlement Agreement.

Please use FMMI code:

for processing this payment.
USDA Agricultural Marketing Service 1400 Independence Avenue SW Room 2646 South Stop 0268 Washington, DC 20250-0268

# fax

TO:	Kevin Edelman	FROM	1: TWilburr	1		
FAX:	(b)(6)	PAGE	S: 2			
PHONE:	(b)(6)	DATE	: 7/16/201	3		
RE:	Signed Agreement	CC:				
🗆 Urgen	t 🛛 For Review	Please Comment	□ Please	Reply	Please Recycle	

Comments:

Kevin,

Please find attached a signed copy of the settlement for your files. We have notified OCIA that we have closed our files on this matter.

Best wishes,

Tammie Wilburn

The Sixty NOPC-081-13 Allegation: 7 CFR 205.100 Previously certified operator selling conventional product as organic. Specialist: T. Wilburn

### Date C&E Chronology

## **Case Synopsis:**

The Sixty was certified as an organic farmer in 2003. The Sixty was effectively suspended in 2010 for failure to conduct an organic seed search and to renew certification. In 2011, OCIA's review of the Sixty's file for reinstatement consideration documented the same noncompliance of failing to conduct seed search. On April 16, 2012, OCIA issued the Sixty a noncompliance for this violation and proceeded to recommend reinstatement of the Sixty to the NOP. Prior to official reinstatement, on April 23, 2012, OCIA issued a prospective Sixty's customer a memo to confirm that the Sixty's organic certification was forthcoming but not yet final. AIA late refuted OCIA's recommendation and denied the Sixty's reinstatement.

Later in 2012, The Sixty again requested reinstatement consideration. OCIA conducted an inspection at the Sixty and discovered the sale of organic product while suspended. OCIA reported this violation to the NOP and issued the Sixty a second Notice of Suspension.

C&E's review of Case NOPC-081-13 finds the continued noncompliance by The Sixty and the documented sale of conventional product as organic while under suspension from organic certification not to be a willful violation of the NOP regulations. The Sixty based the 2012 organic sale on written and verbal confirmation from its accredited certifying agent and proceeded accordingly. Technically, the Sixty violated the regulations, but did not compromise the organic integrity of the product sold as organic.

	2010
•	OCIA issued a Notice of Proposed Suspension to Edelman for failure to respond to a 2008 and a 2009 Notice of Noncompliance (NON). The NON's were issued for failure to conduct a search for organic seeds and for failure to update OSP and submit fees.
<b>*</b> ·	OCIA issued a Notice of Suspension to Edelman as no responses were received to the NON's. OCIA included language in the Notice allowing Edelman to request reinstatement once corrective actions were taken.
	2011
October 14, 2011	OCIA received an application for certification renewal from Edelman.
November 10, 2011	OCIA conducted an on-site inspection at Edelman's. Failure to conduct an organic seed search was noted in the inspection report.
	2012
	OCIA issued a NON to Edelman for failure to conduct an organic seed search and failure to submit a complete OSP. Edelman also farms (b)(4) which was not stated on the OSP.
April 16, 2012	AIA received a request for reinstatement on behalf of Edelman. OCIA notes that noncompliances have been resolved. The resolution per OCIA was a

C&E recommends a small civil penalty be issued to the Sixty (b)(5)

The Sixty NOPC-081-13

Allegation: 7 CFR 205.100 Previously certified operator selling conventional product as organic. Specialist: T. Wilburn

Specialist: T. Wilburn	
	written promise by Edelman to conduct organic seed searches in the future, as well as to update the OSP disclosing conventional farming activities. Noncompliances have a deadline of June 1 <sup>st</sup> for corrective actions.
April 23, 2012	OCIA issued a letter to a possible customer that the Sixty was in the process of getting its organic certification re-instated, but that a decision had not been made by the NOP.
May 5, 2012	AIA's review of OCIA/Edelman's request for reinstatement determined that a recommendation for reinstatement could not be supported. Edelman had been cited for recurring noncompliances since 2007 and the recurring noncompliances should have been elevated to a major noncompliance. OCIA had no evidence that Edelman had taken any action to correct the noncompliances.
May 15, 2012	AIA issued a Denial of Certification to Kevin Edelman via registered mail with cc to OCIA.
September 18, 2012	OCIA received a 2 <sup>nd</sup> letter from Edelman requesting reinstatement.
	OCIA conducted an inspection of Edelman/The Sixty. The inspection showed evidence that Edelman shipped corn to <sup>(b)(4)</sup> on April 25, 2012. Sold a total of <sup>(D)(4)</sup> bushels of corn as organic to <sup>(b)(4)</sup> while suspended.
	OCIA issued Edelman a NON for violation of 205.100 and 102 (selling while suspended) and gave Edelman the option to correct a non-correctable violation. Note: This should have been a Combined NON and Denial of Certification per 205.405(a).
November 7, 2012	
	C&E opens case NOPC 081 -13
	2013
	Edelman sent a letter to the NOP requesting the denial of reinstatement be reconsidered. BR contacted OCIA to ask if they would support his reinstatement. OCIA responded that they could not verify compliance and (b)(6),(b)(7)(c),(b)(7)(d)
January 14, 2013	OCIA issued Edelman a new Notice of Proposed Suspension on January 14, 2013 based on the fraudulent sales with renewal privileges in a year. Mr. Edelman did not appeal the proposed suspension and remains suspended.
	AIA responded by letter to Edelman via registered mail that the NOP needed verification of compliance from his certifying agent before approving reinstatement.
February 1, 2013	Edelman called BR to demand reinstatement. Edelman stated to BR that he had sold his crop as organic. He claimed that OCIA's inspector and certification director told him verbally that he should have no problem with reinstatement, and because of that, he chose sell his crop as organic with the

	understanding that the NOP would eventually reinstate his certificate. He stated that he had always used organic practices, so he did not understand why the NOP couldn't "get past the politics" and just reinstate him so that he could sell his current crop at an organic premium.
April 10, 2013	OCIA forwards Edelmans September 18, 2012, request for reinstatement to AIA. OCIA does not recommend reinstatement.
1 ,	AIA sends Notice of Denial of Reinstatement to Kevin Edelman (certified mail) and OCIA with notice that the matter had been referred to C&E for investigation.

Application for organic certification with any ACA of choice is an independent process from this matter. If you choose to apply for certification again, the ACA will review your request for certification, current compliance and respond accordingly.

This call is to discuss resolution of violations found as a result of a complaint filed against The Sixty. And possibly Mr. Edelman, we can find a way to get you reinstated.

The NOP opened this investigation as a result of an inspection that took place at your place of business. The inspection report revealed continued sales as organic while suspended.

The USDA considers this major violations, and worthy of litigation. If we were to pursue the matter formally, we would file a complaint in court to request our standard penalty for violation of the NOP regulations which is \$11,000 per violation. At this point, the evidence shows that you were effectively suspended in 2012. <sup>(b)(5)</sup>

In lieu of pursuing the violations formally and going through a legal hearing, Mr. Edalman, we are offering to settle out of court with a settlement agreement to resolve the matter. What that means is that we would draft terms under which we agree to settle the matter and offer you a much reduced



USDA Agricultural Marketing Service 1400 Independence Avenue SW Room 2646 South STO 0268 Washington DC 20250-0268

# fax

TO:	Kevin Edelman The Six	ty	FROM:	TWilburn	
FAX:	(b)(6)		PAGES:		
PHONE:	(b)(6)		DATE:	7/2/2013	
RE:	Notice of Penalty and	Settlement	CC:		
🗆 Urger	nt 🗖 For Review	□ Please Comm	nent	□ Please Reply	Please Recycle

Comments:

Kevin,

Please sign and return the Settlement Agreement and return with check. We will notify OCIA upon receipt of settlement.

Thanks,

Tammie Wilburn

From:	Michael, Matthew - AMS
To:	<u>Thornblad, Kristin - AMS</u>
Subject:	FW: New complaint: organic sales under suspension
Date:	Monday, March 18, 2013 3:17:59 PM
Attachments:	image001.jpg Noncompliance US New.doc Edelman Farm IR.doc Susp 41235.doc suspension delivery receipt.pdf

This fell through the cracks – it should be a complaint. Thanks.

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657 matthew.michael@ams.usda.gov

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From: Rakola, Betsy - AMS
Sent: Friday, February 01, 2013 4:46 PM
To: Michael, Matthew - AMS
Cc: Courtney, Cheri - AMS
Subject: New complaint: organic sales under suspension

Dear Matthew,

I received a call today from Kevin Edelman, who has been effectively denied reinstatement by the NOP twice during the last year. In November  $\frac{D(6)(6)}{(2)(e+0)}$  contacted me with evidence that Edelman sold his crop as organic during his suspension. I asked  $\frac{D(6)(6)}{(2)(2)}$  to send this information to C&E, but I don't see the case in the complaints database, so I'm not sure if it ever made it to you.

We denied Edelman's second request for reinstatement on Wednesday via registered mail. This request did not include a supporting letter from OCIA. When I contacted OCIA to ask if they would support the request, <sup>(b)(6),(b)(7)(c),(b)(7)(d)</sup> Because of that, the NOP's response to Edelman included the standard warning language about the possibility of civil penalties of an uncertified operation sells, labels, or represents their product as organic. I just got off the phone with Edelman, who was quite upset – yelling and swearing. I reiterated the reasons for his denial and explained that we cannot reinstate him without supporting evidence of his compliance from a certifier. He replied that he did in fact sell his crop as organic in the spring of 2012, because he was told verbally by the OCIA inspector and certification director that there should be "no problem" with his reinstatement approval from the NOP. I repeatedly

explained the requirements of the regulations and the reinstatement process, but he insisted that he should be reinstated, as he did not consider any of his actions to be problematic.

I'm sending you the attached information  $\frac{|b|(0),(b)(7)(c),(b)}{7(d)}$  as evidence for this complaint case. The chronology log and records of NOP correspondence with Mr. Edelman is at  $\frac{|b|(7)(e)}{2}$ . We have additional correspondence from both Edelman and  $\frac{|b|(6),(b)(7)(c),(b)(7)(d)}{2}$  which may be useful to the compliance specialist who gets this case.

Edelman stated that he had contacted a lawyer and was getting ready to sue, but he did not state whom he intended to sue. I can provide more background to you or your staff, if you need it.

Best,

Betsy Rakola

Agricultural Marketing Specialist, USDA-AMS National Organic Program Tel 202-690-1312 Fax 202-205-7808 www.ams.usda.gov/NOP

From: (b)(6),(b)(7)(c),(b)(7)(d) Sent: Wednesday, November 07, 2012 5:49 PM To: Rakola, Betsy - AMS Subject: organic sales under suspension

Hi Betsy,

(b)(6),(b)(7)(c),(b)(7)(d)	
(b)(6),(b)(7)(c),(b)(7)(d)	we are reporting it to you as hypuld imaging
this would need to go to Compliance and Enforcem questions or if there is anything additional that (7)(c (b)(6),(b)(7)(c),(b)(7)(d) Best,	we are reporting it to you as I would imagine nent. Please let me know if you have any (),(b)(7)(c),(b)
)(6),(b)(7)(c),(b)(7)(d)	

(b)(6),(b)(7)(c),(b)(7)(d)		

# OCIA International, Inc.

**Organic Crop Improvement Association** 1340 North Cotner • Lincoln NE 68505 • USA Phone: (402) 477-2323 • Fax: (402) 477-4325

E-mail: info@ocia.org Web Site: http://www.ocia.org

October 24, 2012

Kevin Edelman The Sixty 24596 E 200 N. Rd. Strawn, IL 61775 Notice of Noncompliance

Reference: Operator # 53745

Dear Kevin Edelman:

The Certification Decision Team (CDT) has reviewed the certification application of "The Sixty" and found the following noncompliances with the following program(s) for which certification is sought. For each instance of noncompliance, a description and the supporting facts are provided. Correction of the noncompliance noted below is not possible. As a result, the CDT has no choice but to continue suspension of certification for "The Sixty", as OCIA cannot recommend that the NOP grant reinstatement of your operation while outstanding noncompliances exist.

1. Sales of crop as certified organic by a suspended operation. [National Organic Program Final Rule 205.100, 205.102].

*Supporting facts:* According to OCIA's records, your operation has been suspended since April 23, 2010. In 2011, your operation requested reinstatement, but was found not to have addressed prior outstanding issues of noncompliance at the time of the reinstatement inspection. As a result, your operation was not granted reinstatement and remained suspended. Your operation was (b)(6),(b)(7)(c),(b)(7)(d) (b)(4).

Please be informed that any certified operator that

knowingly sells or labels a product as organic in the United States, except in accordance with the NOP, shall be subject to a civil penalty of not more than \$11,000 per violation.

You may take one of the following actions in response to each item of noncompliance noted:

- 1. Correct the noncompliance and submit a description of the corrective actions taken with supporting documentation; or
- 2. Submit written information to demonstrate that compliance with the applicable standard exists.

It is necessary for you to provide OCIA with a complete response to the issues noted above **within 30 days** of receipt of this notice in order for your application to remain under consideration for certification. Failure to submit a written response by the deadline provided can lead to issuance of a proposed suspension, denial, or revocation of your operation's organic certificate.

Please contact OCIA if you have questions about items in this notice.

Thank you for your attention to this matter.

(b)(6)	
Ann Tyrdy	

Ann Tvrdy Certification Coordinator



1400 Independence Avenue S.W. Room 2646-S, STOP 0268 Washington D.C. 20250-0268

# **NOTICE OF CIVIL PENALTY**

Kevin Edelman The Sixty 24596 East 200 North Road Strawn, Illinois 61775

Re: NOPC-081-13 The Sixty

Dear Mr. Edelman:

The U.S. Department of Agriculture National Organic Program (NOP) has concluded its investigation of the complaint filed against The Sixty. The complaint alleged that The Sixty lost its organic certification in April 2010 but continued to market and sell its products as "organic" in violation of the USDA organic regulations at 7 CFR 205.

Our investigation confirmed this allegation and documented a shipment of corn sold as organic by The Sixty on May 23, 2012. In response to the investigation, The Sixty has taken the necessary steps to achieve compliance with the regulations and has discontinued its practice of selling its products as organic.

To resolve the violation of record, the NOP is offering to settle this matter informally with the attached settlement agreement and a reduced civil penalty of (0)(5) The agreement is an alternative to initiating a formal administrative proceeding and filing a complaint alleging the above violation of the Organic Foods Production Act. The case would have been heard and decided by an administrative law judge authorized to assess civil penalties of up to \$11,000 per violation.

Please read the enclosed agreement that contains the terms under which the USDA is willing to settle this matter. If you agree to the terms contained therein, please sign the original and return it to the address noted below by July 1010, 2013, along with a certified check or money order made payable to the "Treasurer of the United States."

USDA, National Organic Program Compliance & Enforcement Division 1400 Independence Ave., SW Room 2646-S, STOP Code 0268 Washington, D.C. 20250-0268 Attn: Tammie Wilburn



1400 Independence Avenue S.W. Room 2646-S, STOP 0268 Washington D.C. 20250-0268

Your previous history as an organic farmer and corrective actions in this matter were considered in offering the reduced settlement amount. Please note that this offer does not automatically reinstate the Sixty's organic certification. Once we have received the signed agreement and payment, we will close the investigation. The closed investigation and cleared violation will allow the Sixty to request reinstatement consideration of its organic certification.

If you have any questions regarding this notice, please contact Ms. Wilburn at <u>tammie.wilburn@ams.usda.gov</u> or 202-260-8638.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program

Enclosure - settlement agreement for signature

c)(6),(b)(7)(c),(b)(7)(d)



From:	
То:	Wilburn, Tammie - AMS
Cc:	Mann, Renee - AMS
Subject:	RE: The Sixty NOPC-081-13
Date:	Tuesday, July 23, 2013 10:06:32 AM
Attachments:	image001.jpg



),(b)(7)(c),(b)(7)(d)



From: Wilburn, Tammie - AMS [mailto:Tammie.Wilburn@ams.usda.gov] Sent: Tuesday, July 16, 2013 1:35 PM To:

Cc: Mann, Renee - AMS Subject: The Sixty NOPC-081-13



We are closing out our complaint against The Sixty this week. Mr. Edelman sent in payment and a signed agreement in response to a settlement with civil penalty we recently offered him. The agreement and penalty resolves the violation of record and allows The Sixty to reapply for organic certification. Feel free to contact me if you have questions.

Thanks,

Tammie B. Wilburn

Compliance and Enforcement National Organic Program U.S. Department of Agriculture 1400 Independence Avenue, SW Washington DC 20250 <u>Tammie.Wilburn@ams.usda.gov</u>

202-260-8638 202-205-7808 - *fax* 

Register for the NOP Organic Insider, the National Organic Program's email notification service, by visiting <u>http://bit.ly/NOPOrganicInsiderRegistration</u>.

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.



1400 Independence Avenue, SW. Room 2648-S, STOP 0268 Washington, DC 20250-0268

#### Settlement Agreement

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), Kevin Edelman doing business as The Sixty, and any person responsibly connected with The Sixty, collectively referred to as "the parties."

USDA, AMS and The Sixty have agreed to settle the issues between them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and regulations promulgated thereunder (7 CFR part 205).

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to file a formal administrative complaint charging The Sixty with alleged violation(s) of the OFPA and the regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. The Sixty agrees:
  - A. That it has been given the opportunity for a hearing and waives such hearing and further procedure for the purpose of settling this proceeding and for such purposes only;
  - B. That failure to comply with the settlement agreement shall automatically void paragraph 2 above, and that USDA, AMS may thereafter institute a formal administrative proceeding against The Sixty, and pursue any and all remedies available under the OFPA and the regulations promulgated thereunder; and
  - C. To immediately cease selling, labeling and representing agricultural products in violation of the OFPA and the regulations.
  - D. To pay the reduced civil penalty of \$1,000 for violation of OFPA and in full settlement of this matter.

This agreement will become effective upon receipt of payment.

Date: \_\_\_\_\_

Kevin Edelman Owner The Sixty

Miles McEvoy Deputy Administrator, National Organic Program USDA, AMS Date: \_\_\_\_\_



1400 Independence Avenue, SW. Room 2648-S, STOP 0268 Washington, DC 20250-0268

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  - C. To immediately cease selling, labeling and representing agricultural products in violation of the OFPA and the regulations.
  - D. To pay the reduced civil penalty of \$1,000 for violation of OFPA and in full settlement of this matter.

This agreement will become effective upon receipt of payment.

Date: 7-8-13

Date: 7-15-2013

Kevin Edelman Owner 4 The Sixty

Miles McEvoy Deputy Administrator, National Organic Program USDA, AMS

# OCIA International, Inc. Organic Crop Improvement Association 1340 North Cotner + Lincoln NE 68505 + USA Phone: (402) 477-2323 + Fax: (402) 477-4325 E-mail: info@ocia.org + Web Site: http://www.ocia.org

#### REGISTERED MAIL, RETURN RECEIPT REQUESTED

April 23, 2010

Kevin Edelman The Sixty 24596 E 200 North Rd Strawn, IL 61775-4046 USA NOTICE OF SUSPENSION

Reference: Member # 41265 Producer # 40131G305-04

Dear Kevin Edelman:

A Notice of Proposed Suspension dated February 4, 2010 notified you that certification for The Sixty would be suspended if noted noncompliances with applicable standards were not resolved through mediation or appeal. Because OCIA International has not received any indication of the actions taken on your part to address the Notice of Proposed Suspension, the certification for The Sixty has been **suspended** until all noted issues are adequately addressed and reinstatement by the Secretary of Agriculture is granted.

You are not eligible to use the OCIA name on any crops or products that you produce; to do so would be fraudulent with possible legal repercussions. In addition, you may not use the OCIA Transaction Certificate (TC) system.

Please be informed that an operator who knowingly sells or labels a product as organic in the United States, except in accordance with the NOP, shall be subject to a civil penalty of not more than \$10,000 per violation.

You may at any time, including prior to meeting the stipulations required by OCIA as outlined above, submit a request to the Secretary of Agriculture for reinstatement of your certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance the Act and its regulations.

Respectfully,

b)(6)

Ann Tvrdy Certification Coordinator

cc: IL #1

OCIA: The Worldwide Standard for Certified Organic Excellence



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GLOBAL CULTURE P.O. Box 1640 Crescent City, CA 95531 (707) 464-6913 (707) 464-1802 Fax www.globalculture.us

FEDERALLY ACCREDITED BY THE UNITED STATES DEPARTMENT OF AGRICULTURE, NATIONAL ORGANIC PROGRAM

# **CERTIFICATE OF ORGANIC OPERATION**

**Certified Organic Operation:** 

Larry Magill Magill Ranch, LLC Cascade Feeds, LLC 80419 Wamic Market Road Wamic, OR 97063



Effective Date of Certification: 8/6/05 Revised Date: 6/6/12 Organic Certificate Number: 11-081 Location: 80549 Wamic Market Rd., Wamic, Oregon Category of Organic Operation: Production – Crops Organic Acreage: 243 acres Category of Organic Operation: Processor/Handler

<u>100% Organic</u>: Barley, Dehulled Barley, Barley Hay, Oats, Dehulled Oats, Wheat, Cascade Poultry 3 Grain Scratch

<u>Organic</u>: Cascade Poultry Starter, Cascade Poultry Grower, Cascade Poultry Layer, Cascade Broiler, Cascade Turkey Starter, Cascade Turkey Grower, Cascade Swine Grower

n Hook

Linda Van Hook, Executive Director

Magill Ranch has been certified by Global Culture as compliant with the USDA National Organic Program (7 CFR Part 205). This organic certification shall continue in effect until surrendered, suspended or revoked. Update Organic System Plan by 8/6/12.



### CASE CLOSURE MEMORANDUM

- TO: Matthew Michael Director NOP Compliance & Enforcement Division
- FROM: Sasha Strohm Agricultural Marketing Specialist NOP Compliance & Enforcement Division (C&E)
- SUBJECT: NOPC-185-12 Magill Ranch

CERTIFYING AGENTS INVOLVED: Global Culture

COMPLAINANT: (b)(6),(b)(7)(c),(b)(7)(d)

ALLEGED VIOLATION:

• Subject, Magill Ranch is selling animal feed products as certified organic without certification, in violation of the USDA organic regulations.

#### SUMMARY:

June 11, 2012: The National Organic Program (NOP) C&E Division received a complaint from (b)(6),(b)(7)(c),(b)(7)(d)

The complaint alleged that animal feed purchased from Magill Ranch was adulterated. The complaint also questioned the product's certification status. (Exhibit 1)

Magill Ranch is an Oregon operation that produces a variety of small grains, hay, and beef, and is certified by Global Culture in California. Magill Ranch also produces Cascade Feeds, a line of animal feeds, which is also certified by Global Culture.

(b)(4),(b)(6),(b)(7)(c),(b)(7)(d)

A copy of the Turkey Starter label was included with the complaint and displays the USDA organic seal and Global Culture logo. (Exhibit 2)

(b)(4),(b)(6),(b)(7)(c),(b)(7)(d)



<sup>2</sup> An analysis by CDFA determined that the minimum nutrients guaranteed on the Cascade Feeds Turkey Starter label were deficient in four instances, including a 31% protein deficiency and a 54% fat deficiency. (Exhibits 3-4) The nutrient deficiencies were isolated as the turkeys' cause of death.

Page 2 of 4 NOPC-185-12

- On February 13, 2012, Global Culture issued Magill Ranch a Notice of Noncompliance for selling Cascade Turkey Starter, a noncertified product, as organic. Global Culture requested information on the product by March 15, 2012 to avoid issuing a Notice of Proposed Suspension. (Exhibit 9)
- On February 23, 2012, Magill responded, stating that they made a clerical error by not adding Cascade Turkey Starter to their certification in a timely manner.
   Magill stated that Cascade Turkey Starter was sold to (b)(6),(b)(7)(c),(b)(7)(d)

and had not been produced or sold since. (Exhibit 10) Magill Ranch submitted product profiles and labels to Global Culture for certification of Cascade Turkey Starter, as well as Cascade Pig Grower, Cascade Broiler, and Cascade Turkey Grower.

- On February 24, 2012, Global Culture asked Magill Ranch whether they had sold these products as organic prior to submitting them for approval. In response, Magill stated that the products were not purposely sold as organic; since Magill knew that the buyers were not certified, and the products contained "all organic material," they were sold before being added to Magill Ranch's certification. Magill also stated they had made labels bearing the USDA organic seal in preparation for certification; those labels were "unfortunately" sent with the products.<sup>3</sup> Magill stated these products were sold to only two customers between March 14 and August 22, 2011. (Exhibit 11)
- On May 14, 2012, Global Culture issued Magill Ranch a Notice of Proposed Suspension as Magill Ranch had not adequately corrected the Noncompliance issued on February 13, 2012. Global Culture requested a detailed explanation of the practices and procedures Magill Ranch would follow to prevent future sales of uncertified products as organic. (Exhibit 12) In response, Magill stated that he had established new procedures that would prevent future organic sales without certification. (Exhibit 13)
- On June 4 2012, Global Culture deemed this information sufficient, and issued Magill Ranch a Notice of Resolution of Noncompliance – Proposed Suspension. (Exhibit 14)
- On June 6, 2012, Global Culture updated Magill Ranch's certification to include Cascade Turkey Starter, Cascade Turkey Grower, and Cascade Swine Grower; all of the new products are designated as organic. (Exhibit 15)

Cascade Product	Certification Status
Poultry 3 Grain Scratch	Certified as 100% organic on 1/22/10.
Poultry Starter (aka Starter)	Certified as organic on $1/22/10$ .
Poultry Grower (aka Grower)	Certified as organic on 1/22/10.
Poultry Layer (aka Layer)	Certified as organic on 1/22/10.
Turkey Starter/Bulk	Certified as organic on of 6/6/12.
Turkey Grower/Bulk	Certified as organic on of 6/6/12.
Pig Grower/Bulk	Certified as organic on of 6/6/12 as Swine
	Grower.

<sup>&</sup>lt;sup>3</sup> Note: Magill made this statement on March 15, 2012 regarding sales that occurred in March-August, 2011, but did not submit these labels for approval until May 2012 after Global Culture notified them of the discrepancy.

Broiler/Bulk	Certified as organic on of 6/6/12.

- <u>August 16, 2012</u>: Magill was asked for invoices from January 1, 2011 to June 1, 2012 for all sales of animal feed products by Magill Ranch, as well as Magill Ranch's 2011 year-end financial records.
- August 15, 2012: In a phone discussion with (b)(4),(b)(6),(b)(7)(c),(b)(7)(d)
- <u>November 5, 2012</u>: Magill's invoices from January 1, 2011 to June 1, 2012 were received, along with his 2011 year-end financial records. A review of the records showed only two sales of Cascade Turkey Starter and Cascade Turkey Grower; <sup>(b)(6),(b)(7)(c)</sup>.
   <sup>4</sup> (Exhibit 15A) Other invoices documented sales of organic calcium supplements, organic peas, and organic milk. Magill subsequently provided an organic certificate for the peas from the Montana Department of Agriculture, and stated that the calcium supplement and milk are no longer sold. (Exhibit 16) The calcium supplement was <sup>(b)(4)</sup>

was part of a herdshare, and was inadvertently labeled as organic.

- January 14, 2013: The NOP issued a Notice of Civil Penalty for selling conventional products as organic from January 1, 2011 to June 1, 2012, in violation of § 205.100 of the USDA organic regulations. (Exhibit 17)<sup>5</sup> Magill Ranch was offered a Settlement Agreement and reduced civil penalty in the amount of \$10,000. Negotiations ensued, and Magill agreed to a civil penalty of \$3,000, with monthly installments of \$1,000 payable on the first of each month, beginning March 1, 2013.
- <u>March 5, 2013</u>: Magill's signed Settlement Agreement and first installment payment of \$1,000 were received.

ACTION REQUESTED: This complaint is recommended for closure. Magill Ranch has signed a Settlement Agreement with the NOP and has agreed to a reduced civil penalty of \$3,000 for selling conventional Turkey Starter and milk as organic without certification.

Magill Ranch's website has been updated to state that its Cascade Feeds product formulations have been changed. (Exhibit 18) <sup>(b)(5)</sup>

#### <sup>4</sup>(b)(4),(b)(6),(b)(7)(c),(b)(7)(d)

The Notice of Civil Penalty cited only the sales of conventional Turkey Starter and milk as violations. There was no documented evidence of organic sales of Cascade Turkey Grower.

Page 4 of 4 NOPC-185-12



## VIA EMAIL



#### Dear

Thank you for your June 11, 2012, email referring a complaint against Magill Ranch. The complaint alleged that Magill Ranch was selling conventional products as organic, in violation of the USDA organic regulations.

We conducted an investigation and confirmed the allegation in your complaint. In regard to the violation, the National Organic Program (NOP) and Magill Ranch have reached a settlement, in which Magill Ranch has agreed to pay a civil penalty and also to cease and desist selling, labeling and representing its uncertified products as organic. This investigation is now closed.

Thank you for bringing this matter to our attention. We appreciate your support of the NOP and USDA.

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division National Organic Program

cc: <sup>(b)(6),(b)(7)(c),(b)(7)(d)</sup>



# VIA EMAIL



Re: NOPC-185-12 Magill Ranch



Thank you for your June 11, 2012, email referring a complaint against Magill Ranch. The complaint alleged that Magill Ranch was selling conventional products as organic, in violation of the USDA organic regulations.

We conducted an investigation and confirmed the allegation in your complaint. In regard to the violation, the National Organic Program (NOP) and Magill Ranch have reached a settlement, in which Magill Ranch has agreed to pay a civil penalty and also to cease and desist selling, labeling, or representing its uncertified products as organic. This investigation is now closed.

Thank you for bringing this matter to our attention. We appreciate your support of the NOP and USDA.

Sincerely,

Miles V. McEvoy Deputy Administrator National Organic Program

cc:



VIA UPS

Mr. Larry Magill Magill Ranch 80419 Wamic Market Road Wamic, Oregon 97063 larrymagill@mail.com

Case No: NOPC-185-12 Magill Ranch

Dear Mr. Magill:

Thank you for your response to our Notice of Civil Penalty dated January 14, 2013. Enclosed is a countersigned copy of the Settlement Agreement between the USDA Agriculture Marketing Service and Magill Ranch.

Your cashier's check number <sup>(b)(4)</sup> for **\$1,000.00** has been received as partial payment for the violations associated with case number **NOPC-185-12**. Subsequent payments in the amount of \$1,000 each are due on April 1 and May 1, 2013.

This investigation is hereby closed.

If you have any questions, please contact Sasha Strom in the Compliance & Enforcement Division at (202) 260-8209 or at sasha.strohm@ams.usda.gov.

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division National Organic Program

Enclosure

cc: Director, Accreditation & International Activities Division Linda Van Hook, Global Culture NOP Appeals Team



VIA UPS

MAR 1 2 2013

Mr. Larry Magill Magill Ranch 80419 Wamic Market Road Wamic, Oregon 97063 larrymagill@mail.com

Case No: NOPC-185-12 Magill Ranch

Dear Mr. Magill:

Thank you for your response to our Notice of Civil Penalty dated January 14, 2013. Enclosed is a countersigned copy of the Settlement Agreement between the USDA Agriculture Marketing Service and Magill Ranch.

Your cashier's check number for \$1,000.00 has been received as partial payment for the violations associated with case number NOPC-185-12. Subsequent payments in the amount of \$1,000 each are due on April 1 and May 1, 2013.

This investigation is hereby closed.

If you have any questions, please contact Sasha Strom in the Compliance & Enforcement Division at (202) 260-8209 or at sasha.strohm@ams.usda.gov.

Sincerely,

And Mile

Matthew Michael Director, Compliance and Enforcement Division National Organic Program

Enclosure

cc: Director, Accreditation & International Activities Division Linda Van Hook, Global Culture NOP Appeals Team



# MAR 1 2 2013

VIA EMAIL



Re: NOPC-185-12 Magill Ranch



Thank you for your June 11, 2012, email referring a complaint against Magill Ranch. The complaint alleged that Magill Ranch was selling conventional products as organic, in violation of the USDA organic regulations.

We conducted an investigation and confirmed the allegation in your complaint. In regard to the violation, the National Organic Program (NOP) and Magill Ranch have reached a settlement, in which Magill Ranch has agreed to pay a civil penalty and also to cease and desist selling, labeling and representing its uncertified products as organic. This investigation is now closed.

Thank you for bringing this matter to our attention. We appreciate your support of the NOP and USDA.

Sincerely,

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Matthew Michael Director, Compliance and Enforcement Division National Organic Program

b)(6),(b)(7)(c),(b)(7)(d)

cc:



August 7, 2012

VIA EMAIL

Mr. Larry Magill Magill Ranch 80419 Wamic Market Road Wamic, Oregon 97063 larrymagill@mail.com

Re: NOPC-185-12 Magill Ranch

Dear Mr. Magill:

The U.S. Department of Agriculture National Organic Program (NOP) has received a complaint alleging that Magill Ranch is marketing its products as organic without certification, in violation of the NOP regulations.

The Organic Foods Production Act of 1990 (7 U.S.C. 6501-6522; Act) establishes national standards governing the marketing of certain agricultural products to assure consumers that organically-produced products meet a consistent standard. The NOP regulations (7 CFR Part 205), which implement the Act, require that, unless exempt or excluded, each production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic" products, must be certified by an accredited certifying agent. Any operation that knowingly represents a product as organic, except in accordance with the regulations, shall be subject to a civil penalty of not more than \$11,000 per violation.

Please provide me with a written response to this allegation within 10 days of receipt of this letter, and include supporting documentation, such as information on Magill Ranch's current certification status for its processing and handling of grains, hay, livestock, poultry, crops, and animal feed, and copies of all of Magill Ranch's product labels, including Cascade Feeds Turkey Starter, Turkey Grower, Layer, Pig Grower, Grower, Broiler, Layer Bulk, Grower Bulk, Turkey Starter Bulk, Turkey Grower Bulk, and Broiler Bulk. For information on the National Organic Program, please visit our website at http://ams.usda.gov/nop. I can be reached by phone at (202) 260-8209, or by email at sasha.strohm@ams.usda.gov, should you have any questions.

Re: NOPC-185-12 Magill Ranch Page 2

Thank you for your prompt attention to this matter.

Sincerely,

Sasha Strohm

Sasha Strohm Compliance Specialist National Organic Program



Agricultural Marketing Service 1400 Independence Avenue S.W. Room 2646-S, STOP 0268 Washington D.C. 20250-0268

#### Check Transmittal Memo

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To: Lavern Harris Resource Management Branch Compliance & Analysis Agricultural Marketing Service Room 0725-S

From: Sasha Strohm Compliance & Enforcement Division National Organic Program Agricultural Marketing Service

Date: March 11, 2013

Re: Magill Ranch NOPC-185-12 Settlement Agreement Installment Payment

Enclosed is a <sup>(b)(4)</sup> cashier's check (check number<sup>(b)(4)</sup> from Magill Ranch in the amount of \$1,000.00, as a partial payment of a Settlement Agreement between Magill Ranch and the USDA National Organic Program. This payment satisfies installment one of the \$3,000 Settlement amount.





Agricultural Marketing Service 1400 Independence Avenue S.W. Room 2646-S, STOP 0268 Washington D.C. 20250-0268

#### **Check Transmittal Memo**

To: Lavern Harris Resource Management Branch Compliance & Analysis Agricultural Marketing Service Room 0725-S

From: Sasha Strohm Compliance & Enforcement Division National Organic Program Agricultural Marketing Service

Date: April 3, 2013

Re: Magill Ranch NOPC-185-12 Settlement Agreement Installment Payment

Enclosed is a<sup>(b)(4)</sup> cashier's check (check number <sup>(b)(4)</sup> from Magill Ranch in the amount of \$1,000.00, as a partial payment of a Settlement Agreement between Magill Ranch and the USDA National Organic Program. This payment satisfies the second installment of the \$3,000 Settlement amount.

# Complaint Investigation Chronology Log

## Case #: NOPC-185-12 Subject: Magill Ranch Compliance Specialist: Sasha Strohm

Date	Activity
6/11/12	Rec'd complaint from (b)(6),(b)(7)(c),(b)(7)(d)
	against Magill Ranch for (b)(6),(b)(7)(c),(b)(7)(d) defective
	and adulterated feed manufactured and sold by Magill Ranch). CDFA testing has
	isolated the Magill Ranch feed (b)(6),(b)(7)(c),(b)(7)(d) Feed was defective
	and adulterated. $(b)(4),(b)(6),(b)(7)(c),(b)(7)(d)$ .
	(b)(6),(b)(7)(c),(b)(7)(d)
	(b)(4),(b)(6),(b)(7)(c),(b)(7)(d)
	(b)(6),(b)(7)(c),(b)(7)(d)
	On September 14, 2011, a CDFA
	inspector took samples from the unopened bags of Turkey Starter feed. CDFA
	analyzed the feed and found 4 violations of the CA Food and Agricultural Code,
	confirming that the feed was defective and adulterated.
b)(6),(b)(7)	(c),(b)
(a)	tates that a comparison of the Turkey Starter label and the CDFA Commercial
	Feed Report shows that the feed had dramatic deficiencies in protein and fat essential
	for survival and growth. The CDFA Commercial Feed Report shows that the Turkey
	Starter has a protein deficiency of 31% and a fat deficiency of 54%. The feed also
	contained 150% more salt than shown on the label.
	Series of events:
	• January 3, 2012: (b)(4),(b)(6),(b)(7)(c),(b)(7)(d)
	• Feed label lists nutrients as:
	<ul> <li>Crude protein 24.8%</li> </ul>
	<ul> <li>Lysine 1.64%</li> </ul>
	<ul> <li>Methionine .67%</li> </ul>
	<ul> <li>Crude fat 6.9%</li> </ul>
	• Salt .2933%
	• CDFA Commercial Feed Report showed nutrients as:
	<ul> <li>Crude protein 17.1% (31% deficient)</li> <li>Leving 7849 (529) deficient)</li> </ul>
	<ul> <li>Lysine .784% (52% deficient)</li> <li>Methionine .262% (61% deficient)</li> </ul>
	<ul> <li>Crude fat 3.2% (54% deficient)</li> <li>Salt .51% (154% over label)</li> </ul>
	<ul> <li>February 10, 2012: <sup>(b)(6),(b)</sup>/<sub>(7)(c),(b)</sub> asked ACA to investigate Magill Ranch's</li> </ul>
	compliance with NOP regulations.

(b)(6), (b)(7)(c),
• February 13, 2012: ACA notified that it certified Magill Ranch for
Cascade Poultry 3 Grain Scratch, Poultry Starter, Poultry Grower, and Poultry
Layer. ACA does not certify Magill Ranch for Turkey Starter.
• Certificate for Magill Ranch dated 10/5/09for crop production (wheat,
barley, triticale)
• Certificate for Magill Ranch dated 1/22/10 for crop production and
processing and handling (wheat, triticale, barley, dehulled barley,
Cascade Poultry 3 Grain Scratch, Poultry Starter, Poultry Grower,
Poultry Layer)
• Certificate for Magill Ranch dated 8/25/10 for crop production and
processing/handling (barley, dehulled barley, oats, dehulled oats,
Cascade Poultry 3 Grain Scratch, Poultry Starter, Poultry Grower,
Poultry Layer)
• Certificate for Magill Ranch dated 9/15/11 for crop production and
processing/handling (barley, dehulled barley, barley hay, oats, dehulled
oats, wheat, Cascade Poultry 3 Grain Scratch, Poultry Starter, Poultry
Grower, Poultry Layer)
• February 15, 2012: <sup>(b)(6,0)</sup> asked ACA whether they had initiated an investigation (b)(6)(0)(7) also asked for 1) producers/suppliers of ingredients for
Magill Ranch products $\binom{(b)(4),(b)(6),(b)(7)(c),(b)}{(7)(c),(b)}$ (incl. Turkey Starter, Turkey
Grower, Cascade Layer, Pig Grower, Cascade Grower, Cascade Broiler), 2)
documentation re Magill Ranch sample testing.
• Cascade Turkey Grower label shows product is certified by Global
Culture
$_{O}$ (b)(4),(b)(6),(b)(7)(c),(b)(7)(d)
• February 22, 2012: ACA asked $7(6,6)$ for info on other farmers who may have
purchased feed products from Magill Ranch, and for copies of the labels for
the Turkey Starter, Turkey Grower, or pig feed.
• March 1, 2012: (b)(6), contacted ACA (Global Culture). (b)(6), provided
contact info for 2 growers $(b)(4)$ ) who
purchased Turkey Starter, Turkey Grower, and/or pig feed from Magill Ranch.
The <b>billion</b> purchased feed (Turkey Starter, Turkey Grower, pig feed) from Magill Ranch. The pig feed had USDA organic certification ( <i>no labels</i> )
<i>provided</i> ). Magill Ranch was operating under the name Cascade Feeds. 1)
Who had the USDA organic certification (Magill Ranch, Cascade Feeds, Larry
Magill, or someone else)? 2) Did the labeling showing the UDSA organic
certification for feed sold in 2011 properly reflect the person or entity with the
certification? 3) Have the new entities (Magill Ranch and Cascade Feed)
taken proper steps for use of certification, or are they selling product without
certification?
• April 18, 2012: $\frac{D(6)(0)}{7(0)(0)}$ asked ACA for an update on the status of the
investigation.

	(C)(T) (C),(b) (Z)(d)
	<ul> <li>April 18, 2012: ACA told their investigation is in progress and they would not be contacting him further.</li> <li>April 21, 2012: (0(6).(0)) asked ACA whether investigation is open or closed.</li> </ul>
	<ul> <li>June 11, 2012: <sup>(6)(6),(b)</sup>/<sub>(7)(6),(b)</sub> filed complaint with NOP:</li> </ul>
	• Magill Ranch claims product is certified, but it is not.
	• Magill Ranch's non-certified product is adulterated.
	• ACA was asked to investigate but have not been responsive.
6/22/12	NOP informed block that NOP would open an investigation.
(d)	(c),(b)(7) responded he would check back on July16.
7/18/12	Email from $\frac{10}{7}$ to Matthew Michael requesting a status update.
7/19/12	Email from $\frac{b(6),(b)}{7/(e),(b)}$ reiterating facts of case. $\binom{b}{6},(b)(7)(c),(b)(7)}{(d)}$
8/6/12	Email to $\frac{D(G)(D)}{7(G)(D)}$ requesting copies of product labels from
	Internet research ( <u>www.magillranch.com</u> ):
	• Home: "Larry and Jamie Magill operate the ranch growing a variety of small grains, hay, and beef which has been certified organic since 2005."
	Home: "Magill Ranch also produced Cascade Feeds, which is a Certified Organic, Corn and Soy Free Line of Feeds, since 2009."
	• About: "We produce USDA Certified Organic, Corn and Soy Free feeds, using whole grains."
	<ul> <li>About: "Our pork is raised on our feed we make with all Organic Grains and is soy and corn free."</li> </ul>
	• CSA Shares: "Enjoy Organic, Corn and Soy Free, Free Range Chicken."
	• CSA Shares: "All our beef is Grass Fed on our Organic Pastures. We have our beef slaughtered at a USDA certified facility."
	• Cascade Feeds: Displays USDA organic seal. "USDA Certified Organic." "Magill Ranch Certified Organic Chicken Feed." "Certified Organic. We have certified our farm and feeds USDA Organic so that you can be assured
	the feed you purchase from us has met USDA Organic Standards."
8/7/12	Email to Linda Van Hook at Global Culture requesting all organic certs for Magill Ranch.
	Initial contact letter sent to Magill Ranch. Response due 8/17/12.
8/8/12	Response from Van Hook: Turkey Starter, Cascade Broiler, Turkey Grower were not certified and were being sold as organic with USDA organic seal and Globalculture logo on labels. Magill Ranch stated it was unintentional. Globalculture issued NONC but then issued NONC Resolution when Magill Ranch demonstrated compliance. Products were
	<ul> <li>certified on 6/6/12.</li> <li>August 6, 2005 – Global Culture certified Magill Ranch</li> <li>September 8, 2008 – certification updated for crop production (218 acres wheat and barley)</li> </ul>

•	October 5, 2009 – certification updated for crop production (100 acres wheat, barley, triticale)
•	January 22, 2010 – certification revised for crop production and handling (100 acres; 100% organic wheat, triticale, barley, dehulled barley, Cascade Poultry 3 Grain Scratch; organic Cascade Poultry Starter, Cascade Poultry Grower, Cascade Poultry Layer)
•	August 25, 2010 – certification updated for crop production and handling (100 acres; 100% organic barley, dehulled barley, oats, dehulled oats, Cascade Poultry 3 Grain Scratch; organic Cascade Poultry Starter, Cascade Poultry Grower, Cascade Poultry Layer)
•	July 16, 2011 – certification updated to add crop production for 109 acres of 100% organic apples
•	September 15, 2011 – certification updated for crop production and handling (243 acres; 100% organic barley, dehulled barley, barley hay, oats, dehulled oats, wheat, Cascade Poultry 3 Grain Scratch; organic Cascade Poultry Starter, Cascade Poultry Grower, Cascade Poultry Layer)
•	February 13, 2012 – Global Culture issued NONC to Magill Ranch – Magill Ranch was using a label for Cascade Turkey Starter that displayed the USDA organic seal and Global Culture logo, but Global Culture had no record of certifying this product. Global Culture asked if Magill had sold the product as organic, and whether Magill produced this label.
•	February 23, 2012 – Global Culture rec'd a letter from Magill Ranch, stating they made a clerical error by not registering Turkey Starter with Global Culture. Magill stated they only sold Turkey Starter to (b)(4)
•	February 24, 2012 – Global Culture emailed Magill stating they had rec'd Magill's package re certifying new products. Global Culture asked whether Magill had sold additional products (Pig Grower, Broiler, Turkey Grower, Turkey Starter) to anyone as organic.
•	March 15, 2012 – Magill stated they had not purposely sold Pig Grower, Broiler, Turkey Grower, or Turkey Starter as organic. They used all organic material but sold it to the other customers without certifying it because they knew the customers were not organic. A few times the wrong tag was attached to the product, i.e. they accidentally attached the tag they made bearing the USDA organic seal, which they made before they wanted to certify it. Neither customer requested Magill's organic certificate. These products accounted for (b)(4) of Magill's 2011 sales. Customers were (b)(4) The product was sold between March 14, 2011 and August 22, 2011.
	<ul> <li>March 14, 2011: Grower, Layer, and Pig Grower sold to <sup>(b)(4)</sup></li> <li>All are uncertified.</li> <li>April 18, 2011: Pig Grower, Layer, and Starter sold to <sup>(b)(4)</sup></li> <li>All are uncertified.</li> </ul>
	<ul> <li>May 23, 2022: Pig Grower, Layer, and Starter sold to <sup>(b)(4)</sup></li> <li>All are uncertified.</li> <li>June 21, 2011: Pig Grower, Layer, and Starter sold to <sup>(b)(4)</sup></li> </ul>

	(b)(4) All are uncertified.
	• June 24, 2011: Layer and Broiler sold to (b)(4) All are uncertified.
	<ul> <li>July 13, 2011: Layer, Grower, Pig Grower, Turkey Starter, and Turkey</li> </ul>
	Grower sold to <sup>(b)(4)</sup> All are uncertified.
	• July 25, 2011: Pig Grower, Broiler, Layer, Starter sold to (b)(4)
	All are uncertified.
	• August 3, 2011: Pig Grower, Turkey Starter, Turkey Grower, Grower
	sold to $(b)(4)$ All are uncertified.
	• August 22, 2011: Layer, Broiler, Pig Grower sold to (b)(4)
	All are uncertified.
	<ul> <li>Total above amounts to \$(b)(4)</li> <li>May 14, 2012 – Global Culture issued NOPS to Magill, effective June 25,</li> </ul>
	2012 unless responded to by June 14, 2012, for failure to submit adequate
	resolution to 2/13/12 NONC. Global Culture requested letter detailing Magill
	practices that will prevent future occurrence of sale of animal feed as certified,
	when it is not certified.
	• May 15, 2012 – Letter from Magill stating they have new procedure to ensure
	prevention of unauthorized sales $-(b)(4)$
	• June 4, 2012 – Global Culture issued Notice of Resolution of NONC and
	NOPS on basis that Magill had new practices and procedures in place for submitting product profiles and labels for new organic products prior to selling
	them as organic.
	<ul> <li>June 6, 2012 – certification updated for crop production and handling (243</li> </ul>
	acres; 100% barley, dehulled barley, barley hay, oats, dehulled oats, wheat,
	Cascade Poultry 3 Grain Scratch; organic Poultry Starter, Poultry Grower,
	Poultry Layer, Broiler, Turkey Starter, Turkey Grower, Cascade Swing
	Grower.
	Product labels ( <i>note – product profiles don't seem to match up to label ingredients</i> ):
	Cascade Turkey Starter – contains USDA organic seal and Global Culture logo;
	approved 6/7/12 as 95% organic Cascade Turkey Grower – contains USDA organic seal and Global Culture logo;
	approved 6/6/12 as 95% organic
	Cascade Swing Grower - contains USDA organic seal and Global Culture logo;
	approved 6/7/12 as 95% organic
	Cascade Starter - contains USDA organic seal and Global Culture logo; approved
	9/15/11 as 95% organic
	Cascade Grower - contains USDA organic seal and Global Culture logo; approved as
	95% organic
	Cascade Layer - contains USDA organic seal and Global Culture logo; approved as
	95% organic Cascada 3 Grain Scratch – contains USDA organic seal and Global Cultura logo:
<u> </u>	Cascade 3 Grain Scratch - contains USDA organic seal and Global Culture logo;

	(LABEL ERROR; required revision) Cascade Broiler - contains USDA organic seal and Global Culture logo; approved 6/7/12 as 95% organic
8/14/12	Phone discussion with Linda Van Hook – currently reviewing most recent renewal application (2012). Stated that at 2011 inspection on September 1, 2011, Magill stated they were not selling any other products as organic.
8/14/12	Left voicemail for $\frac{(b)(4),(b)(6),(b)}{(7)(c),(b)(7)(d)}$ re questions re Cascade Feed products purchased in 2011.
8/15/12	Phone discussion with $\begin{bmatrix} b (4)(6)(6)\\ b (7)(6)(6) \end{bmatrix}$ – had problems with Cascade feed products over a year ago (chicken feed – grower/starter; not turkey feeds). Lost $\begin{bmatrix} b (4)\\ chickens$ and determined it was the feed. Switched to another organic feed and problems were resolved. Has no documents/records on file that he can provide, but never purchased turkey products anyway.
8/16/12	Email from Larry Magill asking clarification of what docs I want. Responded asking for all invoices from January 1, 2011 until June 1, 2012 for sales of animal feed products and 2011 year-end financial records.
0/10/10	Magill response – will send docs next week when bookkeeper is back.
9/19/12	Email to Magill. Have not rec'd docs. Asked when we will get them. No response.
10/5/12	Email to Magill. Requested date for documentation. Magill stated docs would go in the mail on that day.
10/17/12	Docs not received. Email to Magill requesting info – were they mailed?
10/19/12	Magill stated they were mailed 10/18
11/5/12	Rec'd docs.
11/8/12	Doc review complete. Email to Magill asking whether Layer is the same as Poultry Layer, etc. and for interpretation of services listed on financial records.
11/14/12	Email from Magill containing definitions requested. Layer, Grower, and Starter are the same as Poultry Layer, Poultry Grower, and Poultry Starter. 2011 sales for Turkey Starter and Turkey Grower match sales records submitted; only sales were to (b)(4)
11/19/12	Email to Magill asking for copy of Organic Calcium Supplement label. Received copy of (b)(4) (b)(4) is manufactured by(b)(4) Discussion with (b)(4) representative (including manager) confirmed that product is not certified organic, nor sold as organic, although they do have other products that are registered for organic input with the WA State Dept of Ag.
12/21/12	Review of Magill sales records shows several sales of organic items—peas, calcium supplement, milk. Magill is not certified for any of these items. Requested organic certificates for each by January 2, 2013.
1/3/13	Email from Magill attaching organic cert for peas (seeds?) and stating no they have no organic cert for calcium supplement, but no longer sells that item. They have no organic certificate for milk; it was a herdshare item but was named wrong on the item list. They no longer sell milk.

1/14/13	Sent Notice of Civil Penalty and Settlement Agreement for \$10,000.
1/23/13	Phone discussion with Magill. Unhappy with \$10K civil penalty. Will submit counteroffer. (541) 544-2087
1/28/13	Rec'd counteroffer from Magill for \$1,000. Responded that NOP will accept \$3,000.
2/5/13	Sent revised documents to Magill for \$3,000. First installment and Settlement Agreement due by 3/1/13.
3/5/13	Settlement and first installment payment \$1,000 received.



VIA UPS

### NOTICE OF CIVIL PENALTY

Mr. Larry Magill Magill Ranch/Cascade Feeds 80419 Wamic Market Road Wamic, Oregon 97063 larrymagill@mail.com

Case No: NOPC-185-12 Magill Ranch

Dear Mr. Magill:

This is an official Notice of Civil Penalty as a result of an investigation into a complaint filed against Magill Ranch on June 11, 2012. This Notice is being issued pursuant to § 205.662(g) of the USDA organic regulations (7 CFR Part 205), which states as follows:

(g) *Violations of Act*. In addition to suspension or revocation, any certified operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the [Organic Foods Production Act of 1990], shall be subject to a civil penalty of not more than [\$11,000] per violation.

. . .

During our investigation of the complaint, we determined that Magill Ranch repeatedly and willfully violated the following provision of the USDA organic regulations:

### Section 205.100 What has to be certified, which states:

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

...

Evidence shows that Magill Ranch repeatedly sold conventional products as organic from January 1, 2011, to June 1, 2012. On several occasions, Magill Ranch sold Cascade Feed Turkey Starter as certified organic; the product label displayed the USDA organic seal and Global
Culture certified organic logo. Prior to June 6, 2012, Magill Ranch was not certified to produce or handle Cascade Feed Turkey Starter. On numerous occasions, Magill Ranch also sold organic milk to its customers. Magill Ranch is not certified to produce or handle organic milk and admitted that the milk was not organic. By representing and selling these conventional products as organic, Magill Ranch violated § 205.100 of the USDA organic regulations.

#### SETTLEMENT

The USDA is willing to settle this matter informally by offering the enclosed Settlement Agreement as an alternative to initiating an administrative proceeding, which would begin with the filing of a complaint alleging the above violation. As a settlement, the NOP proposes to levy a reduced civil penalty of \$3,000.

Please review the enclosed Settlement Agreement containing the terms under which the USDA is willing to settle this matter. If you agree to the terms, please sign the Agreement, and return the original, along with a certified check or money order for your first installment payment of \$1,000 made payable to the "Treasurer of the United States," by March 1 to:

USDA, AMS, National Organic Program Compliance & Enforcement Division Attn: Sasha Strohm Room 2648-S, Stop 0268 1400 Independence Avenue, SW Washington, DC 20250-0268

If you have any questions regarding this Notice of Civil Penalty, please contact Sasha Strohm in the Compliance & Enforcement Division at (202) 260-8209 or sasha.strohm@ams.usda.gov.

Sincerely,

lěs McÉ∳ov

Deputy Administrator National Organic Program

Enclosure



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

VIA UPS

# **NOTICE OF CIVIL PENALTY**

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Sincerely,

Miles McEvoy Deputy Administrator National Organic Program

Enclosure



1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

VIA UPS

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(g) *Violations of Act*. In addition to suspension or revocation, any certified operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the [Organic Foods Production Act of 1990], shall be subject to a civil penalty of not more than [\$11,000] per violation.

(2) Makes a false statement under the [Organic Foods Production Act of 1990] to the Secretary, a State organic program's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of Title 18, United States Code.

During our investigation of the complaint, we determined that Magill Ranch repeatedly and willfully violated the following provision of the USDA organic regulations:

## Section 205.100 What has to be certified, which states:

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

•••

Evidence shows that Magill Ranch repeatedly sold conventional products as organic from January 1, 2011 to June 1, 2012. <sup>(b)(4),(b)(5)</sup>

On numerous occasions, Magill Ranch also sold organic milk to its customers. Magill Ranch is not certified to produce or handle organic milk, and admitted that the milk was not organic. On several occasions, Magill Ranch sold Cascade Feed Turkey Starter as certified organic; the product label displayed the USDA organic seal and Global Culture certified organic logo. Prior to June 6, 2012, Magill Ranch was not certified to produce or handle Cascade Feed Turkey Starter. By representing and selling these conventional products as organic, Magill Ranch violated § 205.100 of the USDA organic regulations.

# SETTLEMENT

The USDA is willing to settle this matter informally by offering the enclosed Settlement Agreement as an alternative to initiating an administrative proceeding, which would begin with the filing of a complaint alleging the above violation. As a settlement, the NOP proposes to levy a reduced civil penalty of  $\binom{(b)(5)}{(b)}$ 

Please review the enclosed Settlement Agreement containing the terms under which the USDA is willing to settle this matter. If you agree to the terms, please sign the Agreement, and return the original, along with a certified check or money order for  $\binom{b}{6}$  made payable to the "Treasurer of the United States," within <u>30 days of receipt</u> of this Notice to:

USDA, AMS, National Organic Program Compliance & Enforcement Division Attn: Sasha Strohm Room 2648-S, Stop 0268 1400 Independence Avenue, SW Washington, DC 20250-0268

If you have any questions regarding this Notice of Civil Penalty, please contact Sasha Strohm in the Compliance & Enforcement Division at (202) 260-8209 or sasha.strohm@ams.usda.gov.

Sincerely,

Miles McEvoy Deputy Administrator National Organic Program

Enclosure



Agricultural Marketing Service 1400 Independence Avenue, S.W. Room 2646-S, STOP 0268 Washington, D.C. 20250-0268

#### VIA UPS

## JAN 14 2013

#### NOTICE OF CIVIL PENALTY

Mr. Larry Magill Magill Ranch/Cascade Feeds 80419 Wamic Market Road Wamic, Oregon 97063 larrymagill@mail.com

Case No: NOPC-185-12 Magill Ranch

Dear Mr. Magill:

This is an official Notice of Civil Penalty as a result of an investigation into a complaint filed against Magill Ranch on June 11, 2012. This Notice is being issued pursuant to § 205.662(g) of the USDA organic regulations (7 CFR Part 205), which states as follows:

(g) *Violations of Act.* In addition to suspension or revocation, any certified operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the [Organic Foods Production Act of 1990], shall be subject to a civil penalty of not more than [\$11,000] per violation.

. . . .

. . .

During our investigation of the complaint, we determined that Magill Ranch repeatedly and willfully violated the following provision of the USDA organic regulations:

#### Section 205.100 What has to be certified, which states:

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

Evidence shows that Magill Ranch repeatedly sold conventional products as organic from January 1, 2011, to June 1, 2012. On several occasions, Magill Ranch sold Cascade Feed Turkey Starter as certified organic; the product label displayed the USDA organic seal and Global

Culture certified organic logo. Prior to June 6, 2012, Magill Ranch was not certified to produce or handle Cascade Feed Turkey Starter. On numerous occasions, Magill Ranch also sold organic milk to its customers. Magill Ranch is not certified to produce or handle organic milk and admitted that the milk was not organic. By representing and selling these conventional products as organic, Magill Ranch violated § 205.100 of the USDA organic regulations.

## SETTLEMENT

The USDA is willing to settle this matter informally by offering the enclosed Settlement Agreement as an alternative to initiating an administrative proceeding, which would begin with the filing of a complaint alleging the above violation. As a settlement, the NOP proposes to levy a reduced civil penalty of \$10,000.

Please review the enclosed Settlement Agreement containing the terms under which the USDA is willing to settle this matter. If you agree to the terms, please sign the Agreement, and return the original, along with a certified check or money order for \$10,000 made payable to the "Treasurer of the United States," within <u>30 days of receipt</u> of this Notice to:

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Sincerely,

Miles McEvoy Deputy Administrator National Organic Program

Enclosure

From:larry MagillTo:Strohm, Sasha - AMSSubject:Re: NOPC-185-12 Magill RanchDate:Thursday, August 16, 2012 2:40:39 PM

Larry Magill Magill Ranch Cascade Feeds 80419 Wamic Mkt Rd. Wamic Or 97063 541-544-2087 541-993-8822

I write this letter in response the complaint about non-organic feed being sold. I have had several conversations with my certifier on this matter. Global Culture has advised me that you also have contacted them for the same information that you have requested from my office. So I am asking for clarification as if you need the duplicated of the information. I am more than willing if need be to do so. Cascade Feeds/Magill Ranch is more than willing to work with you on this complaint to come to a fast resolve for all parties. Please let us know about the information that was requested and any further questions that we may assist in. Thank you for your time. Larry Magill/owner

----- Original Message -----

From: Strohm, Sasha - AMS

Sent: 08/07/12 01:04 PM

To: larrymagill@mail.com

Subject: NOPC-185-12 Magill Ranch

Mr. Larry Magill Magill Ranch 80419 Wamic Market Road Wamic, Oregon 97063 larrymagill@mail.com

Re: NOPC-185-12 Magill Ranch

Dear Mr. Magill:

The U.S. Department of Agriculture National Organic Program (NOP) has received a complaint alleging that Magill Ranch is marketing its products as organic without certification, in violation of the NOP regulations.

The Organic Foods Production Act of 1990 (7 U.S.C. 6501-6522; Act) establishes national standards governing the marketing of certain agricultural products to assure consumers that organically-produced products meet a consistent standard. The NOP regulations (7 CFR Part 205), which implement the Act, require that, unless exempt or excluded, each production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented

as "100 percent organic," "organic," or "made with organic" products, must be certified by an accredited certifying agent. Any operation that knowingly represents a product as organic, except in accordance with the regulations, shall be subject to a civil penalty of not more than \$11,000 per violation.

Please provide me with a written response to this allegation within 10 days of receipt of this letter, and include supporting documentation, such as information on Magill Ranch's current certification status for its processing and handling of grains, hay, livestock, poultry, crops, and animal feed, and copies of all of Magill Ranch's product labels, including Cascade Feeds Turkey Starter, Turkey Grower, Layer, Pig Grower, Grower, Broiler, Layer Bulk, Grower Bulk, Turkey Starter Bulk, Turkey Grower Bulk, and Broiler Bulk. For information on the National Organic Program, please visit our website at http://ams.usda.gov/nop. I can be reached by phone at (202) 260-8209, or by email at sasha.strohm@ams.usda.gov, should you have any questions.

Thank you for your prompt attention to this matter.

Sincerely,

Sasha Strohm

National Organic Program Compliance Specialist 1400 Independence Avenue, SW Room 2641-S, Stop 0268 Washington, DC 20250 (202) 260-8209

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

	(b)(6),(b)(7)(c),(b)(7)(d)
From:	
To:	Michael, Matthew - AMS
Cc:	Thornblad, Kristin - AMS
Subject:	RE: Request for investigation of Magill Ranch
Date:	Friday, June 22, 2012 11:35:38 AM

Mr. Michael

Thank you for advising that an investigation has been opened.

If I don't hear back from you, I will check in on the status of the investigation around July 16, 2012.

If you need any information, please

Sincerely,

(b)(6),(b)(7)(c),(b)(7)(d)	

From: Michael, Matthew - AMS [mailto:Matthew.Michael@ams.usda.gov] Sent: Friday, June 22, 2012 6:15 AM To: Cc: Thornblad, Kristin - AMS Subject: Request for investigation of Magill Ranch



Per your request in your June 11, 2012, correspondence, I am writing to acknowledge its receipt. My office received your request for an investigation of Magill Ranch yesterday. We will treat your correspondence as a complaint and initiate an investigation. We may be contacting you )<sup>(7)(c),(b)</sup>in the course of the investigation.

Sincerely,

Matthew Michael Director, Compliance and Enforcement Division USDA National Organic Program 1400 Independence Ave SW; Room 2959 Washington, DC 20250-0268 Phone: (202) 260-8657

### matthew.michael@ams.usda.gov

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.



1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

# SETTLEMENT AGREEMENT

THIS AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and MAGILL RANCH, collectively referred to as the Parties.

WHEREFORE USDA AMS and MAGILL RANCH have decided to compromise and settle the issues between them related to potential violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 *et seq.*; OFPA), and the USDA organic regulations promulgated thereunder (7 CFR Part 205).

Accordingly, the Parties agree to the following:

- 1. USDA AMS agrees not to file a formal administrative complaint charging MAGILL RANCH with violations of the OFPA and the USDA organic regulations for any actions discovered during the investigation that gave rise to this Agreement.
- 2. MAGILL RANCH agrees to the following:
  - A. MAGILL RANCH has been given the opportunity for a hearing, and waives such hearing and further procedure.
  - B. MAGILL RANCH's failure to comply with the terms of this Agreement shall automatically void paragraph number 1 above, and USDA AMS may thereafter institute enforcement proceedings against MAGILL RANCH, and may pursue any and all remedies available under the OFPA and the USDA organic regulations.
  - C. MAGILL RANCH is assessed a reduced civil penalty of \$3,000, due in installments, using the following payment schedule:

Amount Due	Due Date
\$1,000	March 1, 2013
\$1,000	April 1, 2013
\$1,000	May 1, 2013

D. MAGILL RANCH will immediately cease and desist selling, labeling, or representing any product not certified by a certifying agent authorized to act by USDA AMS pursuant to the OFPA, as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))," as defined by the USDA organic regulations under 7 CFR 250.301(a), (b), and (c). This Agreement shall become effective upon execution by the Parties.

(b)(6)	
Larry Magui	

Owner Magill Ranch

Date  $\frac{2/20/13}{11/13}$ 

les McEvoy Deputy Administrator, National Organic Program USDA Agricultural Marketing Service



1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

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\_\_\_\_

Date \_\_\_\_\_

Larry Magill Owner Magill Ranch

Date \_\_\_\_\_

Miles McEvoy Deputy Administrator, National Organic Program USDA Agricultural Marketing Service

\_\_\_\_\_



Agricultural Marketing Service 1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

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Larry Magill Owner Magill Ranch

Date \_\_\_\_\_

Miles McEvoy Deputy Administrator, National Organic Program USDA Agricultural Marketing Service

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