Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751
Telephone: 407-475-4700
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VIA OVERNIGHT MAIL
SIGNATURE REQUIRED

WARNING LETTER
FLA-13-23
June 18, 2013

Dean W. Martens
President
Herbs of Light, Inc.
P.O. Box 1648
High Springs, FL 32655

Dear Mr. Martens:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 29323 NW County Road 241, Alachua, Florida from September 24 - 28th, 2012. FDA also reviewed the labeling of your products, including your Internet website at http://www.herbsoflight.com, in April 2013. Based on our review of the labeling for your Agrimony, Blood Root, Brown Seaweed, Deer Tick Defense, Echinacea, False Unicorn, Goldenseal, Himalayan Crystal Salts Capsules, Holy Basil, Kidney/Bladder Blend, Lobelia, Mandrake, Olive Leaf, Moringa Botanical Multi-Vitamin, Resistant Microbes, Smoke Out, Thuja, Veins Assist, Vitex, White Oak Bark, Yarrow and Yeast Away products, we have determined that these products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The claims made in the labeling for these products establish that these products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease of the human body. The marketing of these products with these claims violates the Act.

You can find the Act and FDA's regulations through links on FDA's home page at http://www.fda.gov.

Your significant violations are as follows:

Unapproved New Drug

Examples of some of the claims observed in labeling for your products include:

Agrimony (Agrimonia eupatoria, Wildcrafted plant)

- "May be beneficial for dysentery, diarrhea, hemorrhages, prolapsed uterus or anus, and indolent ulcers."

Blood Root (Sanguinaria canadensis, Wildcrafted root)

- "May be beneficial in improving conditions of the skin such as ringworm, warts, polyps, fungal growths…."

Cats Claw (Unicaria tomentosa, Wildcrafted bark)

- "Anti-viral"
- Cilantro Supreme (Wildcrafted/Certified Organic)

"May be beneficial in assisting the body in release Mercury toxicity from within cells."

Deer Tick Defense (Wildcrafted / Certified Organic)

- "[P]roviding safe and significant antimicrobial action. The Cilantro within this blend assists the body in releasing mercury toxicity from within cells, and should be used in conjunction with CHLORELLA, which helps excrete mercury from the cellular membrane."

Echinacea / Goldenseal (Wildcrafted / Certified Organic)

- "Strengthens immune system by stimulating production of white blood cells, and may be beneficial in reducing sub-acute, chronic, mucous membrane inflammation."

False Unicorn (Chamailirium luteum, Wildcrafted root)

- "May be beneficial for female infertility, impotence…"

Goldenseal (Solidago virgaurea, Wildcrafted leaves)

- "A natural antibiotic and antiseptic"

Himalayan Crystal Salts Capsules

- "[B]lood Pressure regulation, Diabetes, Bacterial kill off, Asthmatic attack assistance."
- "For assistance with Lyme Disease or other harmful bacteria …"

Holy Basil (Ocumum sanctum, Organic leaf)

- "[A]nti-inflammatory properties … lowers blood sugar. May protect from carcinogens and chemotherapy toxicity."

Kidney/Bladder Blend (Wildcrafted / Certified Organic)

- "May be helpful for irritated kidney and bladder conditions arising from gravel or stones. Helps with urinary tract discomfort. Decreases water retention."

Kidney/Bladder Blend (Wildcrafted / Certified Organic) Testimonials

- "[Y]our advise [sic] on helping my wife with her kidney stone problem worked wonders. I juiced the watermelon and added two squirts of 'The Herbs of Life Kidney Bladder Supplement'. Within hours her pain began to subside and by this morning the pain is completely gone."

Lobelia (Lobelia inflate, Wildcrafted plant)

- "Great for people who stop smoking"

Mandrake (Podophyllum peltatum, Wildcrafted root)

- "May be beneficial in the elimination of obstruction . . . "

Olive Leaf (Olea europaea, Wildcrafted leaf)

- "[M]ay be helpful in reducing symptoms from yeast, fungal, bacterial, and viral infections."

Resistant Microbes (Wildcrafted / Certified Organic)

- "May be beneficial in reducing fungal, viral and bacterial pathogens."

Rhodiola (Rhodiola rosea, Wildcrafted root)

- "May be effective for … alleviating depression…"

Smoke Out (Wildcrafted / Certified Organic)

- "May be helpful for withdrawal jitters during smoking cessation."

Thuja (Thuja occidentalis, Wildcrafted leaves and young stems)

- "May be beneficial for dysentery."

Veins Assist (Wildcrafted / Certified Organic)

- "[F]or post-surgical operations of the rectum."

Vitex (Vitex agnus castus, Wildcrafted berries)

- "Regulates periods of excessive bleeding and frequency. Used for fibroids, womb inflammation …"

White Oak Bark (Quercus petraea, Wildcrafted bark)

- "May be beneficial for dysentery, diarrhea, hemorrhages, prolapsed uterus or anus, and indolent ulcers"

Yarrow (Achillea millfolium, Wildcrafted flowering plant)

- "May be used as an astringent for bleeding piles, urinary tract, uterus, lungs and hemorrhoids. May also be beneficial for leucorrhoea, menorrhagia and amenorrhea."

Yeast Away (Wildcrafted / Certified Organic)

- “May be beneficial for vaginitis and fungal infections due to candida overgrowth. Provides antiseptic qualities in aiding thrush, parasites, cold sores and intestinal worms”

MRSA / BACTERIA PROTOCOL:

- “Herbs of Light’s Resistant Microbes Blend. Our Resistant Microbes Blend kills fungal, viral and bacterial pathogens

LYME DISEASE HERBAL PROTOCOL

- “Deer Tick Defense: … support while providing safe and significant anti-microbial effects. . . . The natural compounds of Cat’s Claw act as an anti-inflammatory while also providing direct anti-microbial affects [sic]. Recent research with the Cordyceps mushroom has shown … it can assist with those who suffer from Lyme’s energetic deficiency.”
- “Resistant Microbes: This blend is of great value in effecting mutating pathogens when those pathogens are defending themselves from the immune system and other Lyme disease protocols. It is of great assistance also for resistant staph infection or MRSA.”

Moringa Botanical Multi-Vitamin label

- “Its content of … Anti-Bacterials, 36 Anti-inflammatories, Hypotensive and Anticancer Phytochemicals makes it a true Miracle Tree for the World.”

Himalayan Crystal Salt (website):

- “High & Low Blood Pressure … Himalayan Crystal Salts, in conjunction with enough water, is actually essential for the regulation of your blood pressure.”
- “Nature’s Antibiotic … Himalayan Crystal Salts capsules assisted … in getting rid of Lyme disease.”
- “[A]ll bacterial pathogens are affected by Himalayan Crystal Salts”
- “Using salts would stop cholera and typhoid with decided and immediate success in every case.”

Himalayan Crystal Salt brochure:

- “Himalayan Crystal Salts, in conjunction with enough water, is actually essential for the regulation of your blood pressure”.

Himalayan Crystal Salts Capsules & Moringa capsules Testimonials (website)

- “I've been using the Himalyan [sic] Crystal Salts & Moringa from Herbs of Light for several weeks along with dietary changes & supplements … Over the past 2+ years I've been treated for Non-Hodgkins [sic] Lymphoma with Chemotherapy that left me in a constant state of severe Neutropenia, requiring very frequent blood & platelet transfusions, along with receiving "blood booster" shots of Nupogen & Arinesp. My Hematologist at Moffitt Cancer Center in Tampa has stated that I'm now in remission & I told her that I don't want the damn Stem Cell Transplant … It's now been indefinitely postponed! This is the longest period of time I've been able to go without receiving Transfusions of any kind--2 mo. for RBC's & 9 wks. for Platelets.”

Living Foods Brown Seaweed (website)

- “Modern science affirms that an anti-cancer substance called Fucoidan…”
- “Recommended for: Thyroid Problemsâ”€underactive or overactive
- “Helps decrease high blood sugar and cholesterol levels”

Living Foods Brown Seaweed brochure

- “Cancer’s Self Destruction Fucoidan causes certain types of rapidly growing cancer cells to self-destruct. Promoting apoptosis”
- “Laminarin, an essential property of Brown Seaweed, is a polysaccharide helpful in the prevention and treatment of cardiovascular diseases.”

Living Foods brochure – The Importance of Iodine

- “Iodine is:
  - Antibacterial
  - Antiviral
  - Antifungal
  - Antiparasitic
  - Anti-inflammatory”
- “This assists in the prevention of Hashimoto's Disease, Autoimmune disorders…”
- “[L]aundry list of disorders treated with iodine including:
  - Thyroid Disorders

- Cancers (breast, ovarian, thyroid, prostate)
- Breast Disease
- Ovarian Cysts
- Headaches and Migraine"

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" as defined by section 201(p) of the Act [21 U.S.C. § 321(p)]. A new drug may not be legally marketed in the United States without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, because your Agrimony, Brown Seaweed, Deer Tick Defense, False Unicorn, Goldenseal, Himalayan Crystal Salts Capsules, Holy Basil, Kidney/Bladder Blend, Olive Leaf, Moringa Botanical Multi-Vitamin, Resistant Microbes, Thuja, Vitex, White Oak Bark, Yarrow and Yeast Away products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended uses. Thus, your product labeling fails to bear adequate directions for the products' intended uses, causing these products to be misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

Adulterated Dietary Supplements

Even if your products did not have these therapeutic claims, which make them drugs, your products are adulterated within the meaning of section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under conditions that do not meet the Current Good Manufacturing Practice (CGMP) requirements for dietary supplements, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111).

Specifically, during our inspection, our investigators observed the following violations, which were noted on form FDA 483, Inspectional Observations, issued to you on September 28, 2012. We received your written response dated October 10, 2012 to the Form FDA 483. As discussed in more detail below, we find your response inadequate in that you failed to address the serious observations which were presented to you during the inspection of your facility and you failed to provide any documentation that indicates you have begun an effective corrective action plan to bring your firm into compliance with 21 CFR Part 111. You also have not addressed products you have manufactured, marketed, and distributed into commerce without CGMPs in place and which are therefore adulterated under the Act.

Your response to the FDA 483, dated May 31, 2013, was not reviewed however it may be evaluated along with any other written material provided in response to the violations cited in this Warning Letter.

1. You failed to establish specifications for dietary supplements that you manufacture in accordance with 21 CFR 111.70. During the inspection, you verbally confirmed to our investigator that your firm does not have specifications for each component that you use in the manufacture of a dietary supplement. Specifically:

- You did not establish required specifications for points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record [21 CFR 111.70(a)];
- For each component that you use in the manufacture of a dietary supplement, you failed to establish the following component specifications:
  - o Identity specifications [21 CFR 111.70(b)(1)];
  - o Component specifications that are necessary to ensure that specifications for the purity, strength and composition of dietary supplements manufactured using the components are met [21 CFR 111.70(b)(2)]; and
  - o Limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement [21 CFR 111.70(b)(3)];

- You failed to establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplements and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement [21 CFR 111.70(c)(1)];
- You failed to establish specifications for dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications) [21 CFR 111.70(d)];
- For each dietary supplement that you manufacture, you failed to establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement [21 CFR 111.70(e)];

- You failed to establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements including specifications that ensure that you used the specified packaging and that you applied the specified label [21 CFR 111.70(g)].

In your response letter dated October 10, 2012, you agree with the observation, and included a statement about the firm's plans to "document established specifications" without providing details of the actual steps to be taken to correct this violation. Consequently, we could not evaluate the adequacy of your proposed corrections.

2. You failed to prepare and follow a written master manufacturing record (MMR) for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch, as required by 21 CFR 111.205(a). Specifically, you did not prepare a MMR for your Agrimony, Himalayan Crystal Salts Capsules, Black Willow, and Bloodroot dietary supplement products. In addition, you verbally confirmed to our investigator that your firm does not have written MMRs for your products.

In your response letter, dated October 10, 2012, you state that you agree with the observation, and included your intention to complete a written master manufacturing record for your best selling products by the last week of December 2012 and for all of your products by March 2013. However, you have not provided a copy of any written master manufacturing records for your products and therefore we can't evaluate the adequacy of your corrective action.

3. Your batch production record failed to include complete information relating to the production and control of each batch as required by 21 CFR 111.255(b) and 21 CFR 111.260. During the inspection, you provided our investigator with a copy of your "Extraction Control Worksheet" and "Encapsulation Control Sheet" along with batch records for your blended herb liquid extracts and capsules (i.e., Immune booster). However, the batch records you provided do not contain the following required elements:

- The identity of equipment and processing lines used in producing the batch [21 CFR 111.260(b)];
- The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records where this information is retained [21 CFR 111.260(c)];
- The results of any testing or examination performed during the batch production, or a cross-reference to such results [21 CFR 111.260(h)];
- Documentation that the finished dietary supplement meets established specifications [21 CFR 111.260(i)];
- The unique identifier that you assigned to packaging used and the quantity of the labels used [21 CFR 111.260(k)(1)];
- An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the MMR [21 CFR 111.260(k)(2)];
- Documentation at the time of performance that quality control personnel performed required actions [21 CFR 111.260(l)]; and
- Documentation at the time of performance of any reprocessing [21 CFR 111.260(n)].

You state in your response dated October 10, 2012, that you agree with the observation and that you will include all the required information in your batch records by the last week of October 2012. However, you have not provided a copy of any updated batch records to date and therefore we can't evaluate the adequacy of your corrective action.

4. You stated during the inspection that you confirm the identify of components that are not dietary ingredients by relying on a certificate of analysis from the supplier of each component, as set forth in 21 CFR 111.75(a)(2)(ii). However, you failed to first qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examination, as required by 21 CFR 111.75(a)(2)(ii)(A) and you failed to make and keep documents of your qualification of a supplier for the purpose of relying on the supplier's certificate of analysis, as required by 21 CFR 111.95(b)(2). Specifically, you did not provide any information regarding the qualification of your suppliers. You stated at the time of inspection that you only order from reputable manufacturers. However, without additional information, this is not sufficient to meet the requirements of 21 CFR 111.75(a)(2).

In your October 10, 2012 response you address this deviation by stating that you have developed a written procedure by which "herbal components received without C.O.A.s to be put into quarantine until the C.O.A is received" and implemented this effective October 8, 2012. This response is inadequate because it does not address how you will qualify the supplier by establishing the reliability of the supplier's C.O.A., as required by 21 CFR 111.75(a)(2)(ii)(A), how you will maintain documentation of how you qualified the supplier, as required by 21 CFR 111.75(a)(2)(ii)(C), and that you will make and keep records regarding documentation of your qualification of a supplier, as required by 21 CFR 111.95(b)(2).

5. You did not establish and follow written procedures for manufacturing operations, as required by 21 CFR 111.353. Specifically, you have not established written procedures for the following tasks:

- Grinding herbs or powder into finer consistency;
- Blending herbal powders;
- Mixing/combining herbal liquid blends; and
- Pressing herbs during liquid extraction.

Without written procedures, there is no assurance that the dietary supplement products are consistently manufactured to meet specifications. Once you establish and follow your written procedures, you are also required to make and keep records of your written procedures for manufacturing operations as required by 21 CFR 111.375(b).

We have reviewed your response dated October 10, 2012, indicating your intent to create a written procedure for all manufacturing operations involved in the production of your dietary supplements by the 2nd week of February 2013. However, you have not provided any documentation of written procedures that you have developed and therefore we can't evaluate the adequacy of your corrective action.

6. You failed to make and keep written procedures for your production and process control system and receiving records (including records such as certificates of analysis, suppliers' invoices, and suppliers' guarantees) for components, packaging, and labels and for products that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), as required by 21 CFR 111.180(b)(1) and (2). Specifically:

- You did not have records to demonstrate that you visually examine the container or grouping of immediate containers in a shipment that you receive for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the components [21 CFR 111.155(a)];
- You did not have records to demonstrate that you visually examine the supplier's invoice, guarantee, or certification in a shipment you receive to ensure the components are consistent with the purchase order [21 CFR 111.155(b)];
- You did not have records to demonstrate that you quarantine components before you use them in the manufacture of a dietary supplement until you collect a representative sample of each unique lot of components (and, for components the you receive, of each unique shipment, and of each unique lot within each unique shipment) [21 CFR 111.155(c)(1)].

7. You failed to establish and follow written procedures for holding and distributing operations, as required by 21 CFR 111.453. Specifically, you have not established written procedures detailing the required operations to conduct when holding and distributing dietary supplement products, including, but not limited to, the following:

- Holding components and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and dietary supplements are not affected [21 CFR 111.455(a)];
- Holding the packaging and labels under appropriate conditions so that the packaging and labels are not adversely affected [21 CFR 111.455(b)];
- Holding components, dietary supplements, packaging, and labels under conditions that do not lead to the mix-up, contamination, or deterioration of components, dietary supplements, packaging, and labels [21 CFR 111.455(c)];
- Holding reserve samples of dietary supplements in a manner that protects against contamination and deterioration [21 CFR 111.465(a)], including:

o Holding reserve samples of dietary supplements under conditions consistent with product labels or, if no storage conditions are recommended on the label, under ordinary storage conditions [21 CFR 111.465(a)(1)]; and

o Using the same container-closure system in which the packaged and labeled dietary supplement is distributed [21 CFR 111.465(a)(2)]; and

- Retaining reserve samples for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples, for use in appropriate investigations [21 CFR 111.465(b)].

We have reviewed your response dated October 10, 2012 and determined that it is inadequate. You state in your response that you agree with the observation and that you are "establishing a written procedure for the holding inventory and for distributing operations, effective the 4th week of November 2012." However, you have not provided

any documentation of your written procedure for the holding inventory and for distributing operations and therefore we can't evaluate the adequacy of your corrective action.

8. You failed to collect and hold reserve samples of each lot of packaged and labeled dietary supplements that you distributed as required by 21 CFR 111.83(a). Specifically, our investigator did not observe any samples of any lots of packaged and labeled dietary supplements that you had collected or held reserve.

We have reviewed your response dated October 10, 2012 and determined that it is inadequate. You state in your response that you agree with the observation and that you "have begun an initial process for the collection of reserve samples, and will have a process of documenting the reserve of samples for all batches (which will be in the consistent packaging as the product), effective week of October 8, 2012." However, you have not provided any evidence or other documentation to demonstrate that you have implemented a process to collect and hold reserve samples and therefore we can't evaluate the adequacy of your corrective action.

9. You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 CFR 111.103. Specifically, you have not established written procedures for your quality control operations and you verbally confirmed this during our investigation.

We have reviewed your response dated October 10, 2012 and determined that it is inadequate. You state in your response that you agree with the observation and that you "will have a written Quality Control procedure completed by the 4th week of January 2013." However, you have not provided us any documentation of your written quality control procedures and, therefore, we can't evaluate the adequacy of your corrective action.

10. You failed to make and keep records that show that water, when used in a manner such that the water may become a component of the dietary supplement, meets the requirements of 21 CFR 111.15(e)(2), as required by 21 CFR 111.23(c). You also failed to use water that complies with applicable Federal, State, and local requirements for uses such that the water may become a component of a dietary supplement, as required by 111.15(e)(2).

Specifically, you verbally confirmed to our investigator that:

a. You have not established written procedures detailing the testing process and the frequency of testing of the water used as a component of finished batches of dietary supplement products.

b. Your water, originating from two on-site wells, that may become a component of finished batches of dietary supplement products (through contact with any contact surface), was last tested for compliance with applicable Federal, State, and local requirements in October 2012. Additionally, water from the two on-site wells is filtered through a water energizer/distillation machine, prior to being used as a component of finished batches of liquid dietary supplement products, such as single herb and multiple herb blended liquid extracts. Water filtered through this aforementioned machine has not been tested following filtration for compliance with Federal, State, and local requirements for water safety.

We have reviewed your response dated October 10, 2012 and determined that it is inadequate. You state in your response that you will establish a written procedure detailing the water testing process and frequency according to Federal, State, and local requirements by the third week in October, 2012. However, you did not provide any documentation of your written procedure or other evidence that you are complying with the requirements of 21 CFR 111.15(e)(2). Therefore, we cannot evaluate the adequacy of your corrective actions.

11. You did not establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met, as required by 21 CFR 111.303. You also did not make and keep records to provide documentation that the laboratory methodology is followed, including the results of the testing and examination, as required by 21 CFR 111.325(b)(2)(ii). Specifically, your firm performs in-process acceptance testing (for proper color, residue, and transparency) but does not have established written procedures or documentation for this testing or its corresponding results.

We have reviewed your response dated October 10, 2012 and determined that it is inadequate. You state in your response that you agree with the observation and that you "are establishing written procedures for laboratory operations including implementation for organoleptic testing" by the 2nd week of February, 2013. However, you have not provided any documentation of your written procedures for laboratory operations and, therefore, we cannot evaluate the adequacy of your corrective actions.

12. You failed to establish and follow written procedures for handling product complaints as required by 21 CFR 111.553. Specifically, you must establish and follow procedures providing that a qualified person review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet

any of its specifications or any other requirements that, if not met, may result in a risk of illness or injury [21 CFR 111.560(a)(l)].

We reviewed your October 10, 2012 dated response and determined that it is inadequate. You stated in your response that you agree with the observation and have provided a template to document customer complaints. However, your template does not address how a decision will be made to determine whether the complaint involves a possible failure of a dietary supplement to meet any of its specifications.

13. You did not establish and follow written procedures for your packaging and labeling operations, as required by 21 CFR 111.403. Specifically, you have not established written procedures detailing the required operations to conduct when packaging and labeling your dietary supplement products, including but not limited to the following:

- Determining whether the packaging for your dietary supplements meets specifications so that the condition of the packaging will ensure the quality of the dietary supplements [21 CFR 111.410(a)];
- Controlling the issuance and use of packaging and labels, including the reconciliation of any issuance and use discrepancies [21 CFR 111.410(b)];
- Examining, before packaging and labeling operations, the packaging and labels for each batch of dietary supplements to determine whether the packaging and labels conform to the master manufacturing record [21 CFR 111.410(c)];
- Determining the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution [21 CFR 111.410(d)].

In addition, you failed to make and keep records of the written procedures for packaging and labeling operations as required by 21 CFR 111.430(b).

We have reviewed your response dated October 10, 2012, indicating your intent to create written procedures detailing your firm's operations when packaging and labeling your dietary supplements by the 4th week of November 2012. However, your response is inadequate because you did not provide any supporting documentation of your corrective action.

14. You failed to make and keep written procedures for returned dietary supplements, as required by 21 CFR 111.535(b)(1). Specifically, you did not have written procedures for handling any returned dietary supplements, including when a returned dietary supplement may be salvaged in accordance with 21 CFR 111.520, or when a returned dietary supplement must be destroyed or otherwise suitably disposed of in accordance with 21 CFR 111.515.

We have reviewed your response dated October 10, 2012 and determined that it is inadequate. You stated in your response that you agree with the observation and that you are "establishing a written procedure for what to do when a returned herbal supplement is returned," and that the written procedures will be completed and you will begin to implement them by the 2nd week of November 2012. However, you have not provided a copy of your written procedures for returned dietary supplements and, therefore, we cannot evaluate the adequacy of your corrective action.

Misbranded Dietary Supplements

Further, even if your products listed below did not have the therapeutic claims referenced above, which make them drugs, they are misbranded dietary supplements within the meaning of section 403 of the Act [21 U.S.C. § 343] and its implementing regulations in 21 CFR Part 101, as discussed further below.

1. Your Agrimony, Alfalfa, Angelica, Bitter Melon, Black Willow, Bladderwrack, Blood Root, Blue Cohosh, Broccoli Defense, Cat's Claw, Chaparral, Cleavers, Damiana, Dandelion Root, Devil's Club, Dong Quai, Goat's Rue, Graviola, Green Tea, Guggul, Hawthorn, Himalayan Crystal Salts Capsules, Holy Basil, Khella, MaiReiShiitake Mushroom, Maitake Mushroom, Marshmallow, Mistletoe, Moringa Botanical Multi-Vitamin, Ovary / Uterus, Poke Root, Reishi Mushroom, Resistant Microbes, Shiitake Mushrooms, Stevia, Turmeric, and Venus Fly Trap labels are misbranded within the meaning of Section 403(y) of the Act [21 U.S.C. 343(y)] in that the labels fail to include a complete domestic address or domestic phone number through which the responsible person (as described in section 761(b)) may receive a report of a serious adverse event with such dietary supplement.

2. Your Agrimony, Alfalfa, Angelica, Bitter Melon, Black Willow, Bladderwrack, Blood Root, Blue Cohosh, Broccoli Defense, Cat's Claw, Chaparral, Cleavers, Damiana, Dandelion Root, Devil's Club, Dong Quai, Goat's Rue, Graviola, Green Tea, Guggul, Hawthorn, Himalayan Crystal Salts Capsules, Holy Basil, Khella, MaiReiShiitake Mushroom, Maitake Mushroom, Marshmallow, Mistletoe, Moringa Botanical Multi-Vitamin, Ovary / Uterus, Poke Root, Reishi Mushroom, Resistant Microbes, Shiitake Mushrooms, Stevia, Turmeric, and Venus Fly Trap product labels are misbranded within the meaning of Section 403(e)(1) of the Act [21 U.S.C. 343(e)(1)] because the label fails to list the

place of business of the manufacturer, packer, or distributor as required by 21 CFR 101.5(a) and (d). The labels in use at the time of the inspection only list the name of the business and the firm's website www.herbsoflight.com.

3. Your Alfalfa, Bladderwrack, Blue Cohosh, Cat's Claw, Dandelion Root, Green Tea, Hawthorn, Himalayan Crystal Salts Capsules, Holy Basil, Marshmallow, Moringa, Ovary/Uterus, Resistant Microbes, Turmeric and Venus Fly Trap product labels are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. 343(i)(2)] in that the dietary ingredients are contained in capsules, but the capsule ingredients are not listed on the label in accordance with 21 CFR 101.4(g).

4. Your Agrimony, Alfalfa, Angelica, Bitter Melon, Black Willow, Bladderwrack, Blood Root, Blue Cohosh, Broccoli Defense, Cat's Claw, Chaparral, Cleavers, Damiana, Dandelion Root, Devil's Club, Dong Quai, Goat's Rue, Graviola, Green Tea, Guggul, Hawthorn, Himalayan Crystal Salts Capsules, Holy Basil, Khella, MaiReiShiitake Mushroom, Maitake Mushroom, Marshmallow, Mistletoe, Ovary / Uterus, Poke Root, Reishi Mushroom, Resistant Microbes, Shiitake Mushrooms, Stevia, Turmeric, and Venus Fly Trap product labels are misbranded within the meaning of Section 403(q)(5)(F) of the Act [21 U.S.C. 343(q)(5)(F)] because they fail to bear nutrition information ("Supplement Facts" panel) in accordance with 21 CFR 101.36.

5. Your Agrimony, Alfalfa, Cleavers, MaiReiShiitake Mushroom, Maitake Mushroom, Mistletoe, Moringa Botanical Multi-Vitamin, Ovary / Uterus, Reishi Mushroom, Resistant Microbes, and Shiitake Mushrooms product labels are misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)], in that the label fails to identify the part of the plant from which one or more of the botanical dietary ingredients in the product are derived, as required by 21 CFR 101.4(h)(1). For example, your Reishi Mushroom label fails to identify the part of the mushroom used (e.g., mycelium, stalk, cap, or whole mushroom).

This letter is not intended to be an all-inclusive list of violations which exist in connection with your products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct the violations described above and prevent their further recurrence. Failure to promptly correct these violations may result in enforcement action, without further notice, including, without limitation, seizure and/or injunction.

In addition to the above violations, we have the following comments:

- 21 CFR 111.25 requires that you establish and follow written procedures for fulfilling the requirements for equipment and utensils. However, we did not identify written procedures for (a) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement; (b) Calibrating, inspecting and checking automated, mechanical and electronic equipment; or (c) Maintaining, cleaning and sanitizing, as necessary, all equipment, utensils and other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements.
- 21 CFR 111.14(b)(1) requires that you make and keep written procedures for determining personnel qualifications requirements. However, we did not identify written procedures for verifying that all employees involved in the operations of your firm such as manufacturing, packaging, labeling, or holding or in performing any quality control operations are qualified by education, training, or experience to perform their assigned functions to comply with 21 CFR 111.12(c).

Further, 21 CFR 111.14(b)(2) requires that you make and keep documentation of training, including the date of the training, the type of training, and the person(s) trained. However, we did not identify such documentation. . Specifically, you were unable to provide any documentation to indicate that you have performed training of your personnel. Our investigator was informed by the Office Manager, that when hired, employees are trained via on-the-job training, then rotated through the different stages of the manufacturing process and further cross-trained in all aspects of the manufacturing process over their term of employment.

In your response letter dated October 10, 2012, you provided a brief SOP for "Qualifying Employees" with the intent to provide written "Employee Training Operations" by the 2nd week of December 2012. You also stated in your letter that you would be sharing with the agency an "Employee Training Video" as soon as available, which at present has not been received. However, you failed to provide any documentation or other evidence demonstrating that this training program has been implemented. Consequently, we are not able to evaluate your corrective action at this time and will verify your procedures and documentation of training at the next scheduled inspection of your firm.

- During the inspection you indicated to the FDA investigator that you were unaware of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, effective 12/22/07, or Section 761 of the FD&C Act, which contains the reporting requirement for adverse events. Under section 761 (c) of the Act, you must submit a report of a serious adverse event no later than 15 business days after the report is received through the address or phone number described in section 403(y) of the Act. Because prompt submission of serious adverse event reports is important for public health reasons, we recommend that all serious adverse event reports be reported to

FDA within 15 business days of receipt (regardless of the means by which you receive the initial report). More information on adverse event reporting can be found online in the publication "Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act," revised in June 2009, available on our website, www.fda.gov.

- Some of the firm's products labeled as dietary supplements are not intended for ingestion, and are therefore not consistent with the statutory definition of a dietary supplement (Section 20l(ff)(2)(A)(i) of the Act). Hence such products do not qualify as dietary supplements. For example, "Eyesight Blend", labeled as a dietary supplement, is an ophthalmic solution (i.e., not "intended for ingestion") and therefore does not qualify as a dietary supplement. Another example is "Himalayan Crystal Salts", which has a bath detoxification regimen included with other instructions in the brochure, but the bottle of capsules labels the product as a dietary supplement.
- We suggest that you have data to support the "expiration dates" established in your firm's finished product specifications and applied to your firm's finished dietary supplement products, including Moringa Botanical Multi-Vitamin which is labeled with an expiration date of 9/04/2022 (see 72 FR 34752 at 34856; June 25, 2007).

Section 743 of the Act [21 U.S.C. § 379j-31] authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determining whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses incurred in connection with FDA's arranging, conducting, and evaluating the results of the re-inspection and assessing and collecting the re-inspection fees [21 U.S.C. § 379j-31(a)(2)(B)]. For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility.

Please respond in writing within fifteen working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct the violations noted above and the steps you are taken to prevent their recurrence. You should include in your response documentation and any other useful information that would assist us in evaluating your corrections. If you cannot complete these corrective actions within fifteen working days, state the reason for the delay and the date by which you will have completed the correction.

Please send your written reply to the Food and Drug Administration, Attention: Ms. Carla Norris, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have questions regarding any issues in this letter, please contact Ms. Norris at (407) 475-4730.

Sincerely,
/S/
Emma R. Singleton
District Director
Florida District Office

cc:
Herbs of Light, Inc.
29323 NW County Road 241
Alachua, FL 32615-3272