

WARNING LETTER

Evig LLC dba Balance of Nature

MARCS-CMS 580888 – AUGUST 20, 2019

Delivery Method:

VIA UPS

Reference #:

HAF4W(DEN)-19-09-WL

Product:

Food & Beverages

Recipient:

Douglas L. Howard
Chief Executive Officer
Evig LLC dba Balance of Nature
785 E. Venture Dr.
St. George, UT 84790
United States

Issuing Office:

Division of Human and Animal Food Operations West IV
United States

August 20, 2019

WARNING LETTER

Ref: # HAF4W (DEN)-19-09-WL

Dear Mr. Howard:

On February 4 – 8, 2019, the U.S. Food and Drug Administration (FDA or we) inspected your facility located at 785 E. Venture Dr., St. George, UT. During the inspection, our investigator collected product labels and written material accompanying your products. In addition, we reviewed labeling on your firm's website at www.balanceofnature.com and

your YouTube channel at www.youtube.com/user/balanceofnature1. The inspection and our review of your product labeling revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. You can find the Act and its implementing regulations through links on FDA's home page at www.fda.gov.

We acknowledge receipt of your response to the FDA-483, Inspectional Observations, dated February 18, 2019, and we address your response below.

Unapproved New Drugs/ Misbranded Drugs

FDA reviewed your website at the Internet address www.balanceofnature.com and your YouTube channel at www.youtube.com/user/balanceofnature1 in July 2019 and has determined that you take orders on your website for your Whole Food Fruits, Whole Food Veggies, and Whole Food Fiber & Spice products. Your website links to your YouTube channel and your YouTube channel links back to your website. In addition, we reviewed the product labels and written material accompanying your shipments collected during the inspection. The claims on your product labeling, including your website and YouTube channel, establish that these products are 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)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include:

Whole Food Veggies capsules:

- Product pamphlet titled "Quick Tips for Quick Relief" that accompanies the product in shipping boxes: "Do you have an itchy, sore, or scratchy throat? Sprinkle the contents of 3-6 Veggies capsules into a cup of warm broth, stir together and drink. Also, keep a few extra fruit capsules in your pocket to chew on when you feel symptoms coming on These two tricks will . . . soothe your throat and ease coughing . . . When flu, cold, or allergy seasons come around double up at the beginning and throughout the season . . . You'll be amazed at how fast you'll kick it!"

Whole Food Fiber & Spice:

Statements on the product label:

- "Diabetics: Proven safe and effective for diabetics. Studies demonstrate that polyphenol compounds found in Fiber & Spice improve insulin sensitivity leading to improved insulin function."
- "Arthritis: Many of the phytochemicals found in Fiber & Spice have been shown to possess anti-inflammatory properties."
- "Lower cholesterol: Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium husk, as in Fiber & Spice, may reduce the risk of heart disease by lowering cholesterol."

Whole Food Fruits, Whole Food Veggies, and Whole Food Fiber & Spice:

- From the webpage "Whole Health System" on your website www.balanceofnature.com: "By taking these supplements consistently, you'll begin to feel the positive effects of . . . Fiber consumption and its cholesterol reducing properties"
- From the video posted to your YouTube channel, *How to Help Overcome Relapsing MS*:
 - The name of the video constitutes a claim that your products are intended for use in the cure, mitigation, treatment, or prevention of Multiple Sclerosis (MS).

- From the video description: “Marie explains her daughter’s situation with MS and how Balance of Nature’s Fruits and Veggies have helped her with the energy and strength to fight her condition. Please share this with people you know fighting this same condition. . . Balance of Nature will give you over 10 servings of fruits and vegetables every day. ‘The American Institute for Cancer Research’ and the ‘USDA’ have confirmed that eating 9 to 11 servings of fruits and vegetables every day is the key to preventing cancer and other lifestyle diseases.”
- From *Real Balance of Nature Customer with MS* video page posted to YouTube channel:
 - The name of the video constitutes a claim that your products are intended for use in the cure, mitigation, treatment, or prevention of Multiple Sclerosis.
- From *No More Inhalers for Her Asthma* video posted to YouTube channel:
 - The name of the video constitutes a claim that your products are intended for use in the cure, mitigation, treatment, or prevention of asthma.
 - From the video description: “Balance of Nature has helped Janna with her allergies. She no longer needs her Asthma inhaler [S]he has also seen improvements in her skin as she visited her dermatologist for quarterly skin cancer checkups.”
- From *How to Stay Healthy & Physically Active at 80 Years Old* video posted to YouTube channel:
 - From the video description: “Now, with the ‘wheelbarrow fulls’ of real food that she gets with Balance of Nature, she hasn’t had pneumonia in 5 years.”

Your YouTube channel also contains additional evidence of intended use in the form of personal testimonials recommending or describing the use of the products for the cure, mitigation, treatment, or prevention of disease.

Examples of such testimonials include:

- From the video posted to your YouTube channel, *How to Eat Natural Healthy Whole Food with a Busy Lifestyle – Prostate PSA Success Story*:
 - (4:15) “Aside from cancer I know Balance of Nature helps with the smaller illnesses the kind of the day-to-day illnesses. For myself in two years that I’ve been on it I don’t even think I’ve had a cold not never mind the flu not even nothing close to the flu.”
- From *Real Balance of Nature Customer with MS* video page posted to YouTube channel:
 - (1:42) “after maybe three years I think that was look [sic] was that the first time I had an MRI without any new active lesions being on balance of nature”
- From *How to Stay Healthy & Physically Active at 80 Years Old* video posted to YouTube channel:
 - (1:10) “I’ve had some health issues...I’ve had pneumonia I can’t even tell you how many times... I did not even have a bad cold this whole last winter and I think that’s due to my being very diligent in taking my Balance of Nature...”
- From *No More Inhalers for Her Asthma* video posted to YouTube channel:
 - (2:06) “One of the best things about these [Balance of Nature products] is people with asthma, they say it goes away.”
 - (2:29) “Went from all this asthma medication to none . . . no more asthma symptoms.”
 - (2:41) “The second benefit [of Balance of Nature], I had skin cancer when I was 21, a melanoma . . . every three months I would go into the dermatologist and, you know, get moles removed . . . within a year after

taking this [Balance of Nature products] my dermatologist [said] . . . well, you're fine, you don't need to come back every 3 months"

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1) (A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products Whole Food Fruits, Whole Food Veggies, and Whole Food Fiber & Spice are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your Whole Food Fruits, Whole Food Veggies, and Whole Food Fiber & Spice products fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

Adulterated Dietary Supplements

Even if the labeling of your Whole Food Fiber & Spice, Whole Food Veggies, and Whole Food Fruits products did not have therapeutic claims that make them unapproved new drugs, the products would be adulterated within the meaning of section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] because the products 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), as follows:

1. You failed to implement a system of production and process controls to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.55. Specifically, you have not established and implemented a system of production and process controls.

As a distributor that contracts with other manufacturers to manufacture, package, and label dietary supplements for distribution under your firm's name, your firm has an obligation to know what and how manufacturing, packaging, and/or labeling activities are performed so that you can make decisions related to whether your dietary supplement products conform to established specifications and whether to approve and release the products for distribution [72 Fed. Reg. 34752, 34790 (Jun. 25, 2007)]. Your firm introduces or delivers, or causes the introduction or delivery of, the dietary supplement into interstate commerce in its final form for distribution to consumers. As such, your firm has an overarching and ultimate responsibility to ensure that all phases of the production of that product are in compliance with dietary supplement CGMP requirements.

During the inspection, management stated that your firm distributes proprietary dietary supplement products under your brand names and that these dietary supplement products are manufactured for your firm by a contract manufacturer. Although a firm may contract out certain dietary supplement manufacturing operations, it cannot contract out its ultimate responsibility to ensure that the dietary supplement it places into commerce (or causes to

be placed into commerce) is not adulterated for failure to comply with dietary supplement CGMP requirements. [See *United States v. Dotterweich*, 320 U.S. 277, 284 (1943) (explaining that an offense can be committed under the Act by anyone who has “a responsible share in the furtherance of the transaction which the statute outlaws”); *United States v. Park*, 421 U.S. 658, 672 (1975) (holding that criminal liability under the Act does not turn on awareness of wrongdoing, and that “agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act” can be held accountable for violations of the Act)]. In particular, the Act prohibits a person from introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce a dietary supplement that is adulterated under section 402(g) for failure to comply with dietary supplement CGMP requirements (see 21 U.S.C. 342(g) and 331(a)).

Thus, a firm that contracts out some or all of its operations must establish a system of production and process controls 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 111.55). The quality control personnel must ensure that the manufacturing, packaging, labeling, and holding operations 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 111.105).

2. 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 and 21 CFR 111.140(b)(1). Specifically, you do not have written procedures for responsibilities of the quality control operations and you do not document any of the required quality control operations for the processes you perform, such as approval of contract manufacturers, approval of raw material suppliers, approval of formulations, and approval of labels.

We have reviewed your letter, dated February 18, 2018, which states that you are currently working on developing written quality control procedures. We are unable to evaluate the adequacy of your response because you did not provide any documentation of the quality control procedures.

3. You failed to establish and follow written procedures to fulfill the requirements related to product complaints, as required by 21 CFR 111.553, and for the review and investigation of product complaints, as required by 21 CFR 111.560. Specifically, you do not have any written procedures for product complaints.

We have reviewed your letter dated February 18, 2019, which states that you are currently working on procedures for how each complaint is reviewed and investigated. We are unable to evaluate the adequacy of your response because you did not provide any documentation of the product complaint procedures.

Once you have established the procedures required by 21 CFR 111.553 and 21 CFR 111.560, you must maintain written records of every complaint related to good manufacturing practice and records of the findings of any investigation and follow-up action when an investigation is performed, as required by 21 CFR 111.570(b)(2).

Misbranded Dietary Supplements

Even if your Whole Food Fruits, Whole Food Veggies, and Whole Food Fiber & Spice products were not unapproved new drugs, they would still be misbranded foods within the meaning of section 403 of the Act [21 U.S.C. § 343]. Specifically, our review of your product labels revealed that your products are misbranded within the meaning of section 403 of the Act as follows:

1. Your Whole Food Fiber & Spice product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is misleading because it fails to state a material fact [see section 201(n) of the Act (21 U.S.C. § 321(n))]. Specifically, the product contains dry or incompletely hydrated psyllium husk, and

the product label bears the following health claim on the association between soluble fiber from psyllium husk and reduced risk of coronary heart disease: “Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium husk, as in Fiber & Spice, may reduce the risk of heart disease.” Under 21 CFR 101.17(f), foods containing dry or incompletely hydrated psyllium husk that bear a health claim on the association between soluble fiber and reduced risk of coronary heart disease, see 21 CFR 101.81, must bear a label statement informing consumers that the appropriate use of such foods requires consumption with adequate amounts of fluids, alerting them of potential consequences of failing to follow usage recommendations, and informing persons with swallowing difficulties to avoid consumption of the product. However, the label of your Whole Food Fiber & Spice bears no such required warning statement.

2. Your Whole Food Fiber & Spice powder, Whole Food Fruits capsules, and Whole Food Veggies capsules products are misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. § 343(q)(5)(F)] in that the presentation of the nutrition information on the labels does not comply with 21 CFR 101.9 and 21 CFR 101.36. For example:
 - a. Your Whole Food Fiber & Spice product label fails to round the values for the (b)(2) ingredients in accordance with 21 CFR 101.9(c)(6). The label bears an incorrect %DV for total carbohydrate based on the quantitative amount declared per serving.
 - b. Based on the declaration of total carbohydrate and total omega fatty acids on the Whole Food Fiber & Spice product label, the label is not in compliance with 21 CFR 101.36(b)(2): the (b)(2)-dietary ingredients to be declared, that is, total calories, calories from fat, and total fat, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with 101.9(c). However, total calories, calories from fat, and total fat are not declared on the product label.
 - c. Your Whole Food Fiber & Spice product label declares dietary fiber in an amount that is greater than the quantitative amount declared for total carbohydrate. Total carbohydrate must be greater than or equal to the sum of carbohydrate components including dietary fiber and total sugar.
 - d. Your Whole Food Fiber & Spice product label’s other 21 CFR 101.36(b)(3) dietary ingredients must bear a symbol (e.g., an asterisk) in the column under the heading of “% Daily Value” that refers to the same symbol placed at the bottom of the nutrition label and followed by the statement, “Daily Value not established.” 21 CFR 101.36(b)(3)(iv).
 - e. Your Whole Food Fruits capsules and Whole Food Veggies capsules product labels do not list the dietary ingredients in the proprietary blend in descending order of predominance by weight as required by 21 CFR 101.36(c)(2); and the quantitative amount of the proprietary blend is not placed on the same line to the right of the term “Proprietary Blend” as required by 21 CFR 101.36(c)(3).
 - f. Your Whole Food Fiber & Spice product label presents the “Ingredients list” within the Supplement Facts label. The label must present the ingredient statement outside and immediately below the Supplement Facts box and the ingredients must be listed in descending order of predominance by weight in accordance with 21 CFR 101.4(a) and 21 CFR 101.4(g). Furthermore, the Supplement Facts box includes terms that are not permitted, such as “Ingredients,” “no added sugars” and “no artificial sweetener,” 21 CFR 101.9(c).
 - g. Your Whole Food Fruits capsules and Whole Food Veggies capsules product labels bear a symbol (that is, an asterisk) which refers to the same symbol placed at the bottom of the nutrition label that is followed by the statement “Daily Value not established” in accordance with 21 CFR 101.36(c)(3), but the symbol is placed immediately after the term “Proprietary Blend.” The symbol must be placed immediately following the quantitative amount by weight for the proprietary blend.

- h. Your Whole Food Fruits capsules, Whole Food Veggies capsules, and Whole Food Fiber & Spice powder products' formatting of the Supplement Facts label is not in accordance with 21 CFR 101.36(e), specifically with respect to the use of heavy bar, light bars, and hairline rules and/or the "Supplement Facts" type size.
3. Your Whole Food Fruits capsules and Whole Food Veggies capsules products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product labeling bears nutrient content claims but fails to comply with the requirements for making such claims. Specifically, the labels of the Whole Food Fruits capsules and Whole Food Veggies capsules products bear the claim, "More antioxidant power than any other brand."

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation authorizing the use of such a claim. Characterizing the level of a nutrient on the food labeling of a product without complying with the specific requirements pertaining to the nutrient content claim for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must comply with, among other requirements, the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a reference daily intake (RDI) must have been established for each of the nutrients that are the subject of the claim, as required by 21 CFR 101.54(g)(1), and these nutrients must have recognized antioxidant activity, as required by 21 CFR 101.54(g)(2). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity, as required by 21 CFR 101.54(g)(4). The above quoted antioxidant claim on your product labels is a nutrient content claim because it characterizes the level of antioxidants in your products, but they do not comply with 21 CFR 101.54(g)(4) because the label does not include the names of the nutrients that are the subject of the claim.

Additionally, the claim "More antioxidant power than any other brand" is a "relative claim." The claim fails to include the accompanying information for relative claims as required by 21 CFR 101.13(j). In order to bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared to an amount of nutrient in an appropriate reference food as specified under 21 CFR 101.13(j)(1) and the label or labeling must state the identity of the reference food under 21 CFR 101.13(j)(2).

4. Your products Whole Food Fruits capsules and Whole Food Veggies capsules are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that the product labels fail to declare all the common or usual names of each ingredient used as required by 21 CFR 101.36 and 21 CFR 101.4. Specifically, the products are encapsulated but the labels fail to list the capsule ingredients.

Additionally, your Whole Food Veggies capsules product declares "yam" as part of the proprietary blend whereas the product's batch record for lot #20191401 (from **(b)(4)** inspection ending 2/8/2019) lists "wild yam." These are two different botanical ingredients – the label must state the common or usual name for the dietary ingredient used in the product.

5. Your Whole Food Fruits capsules, Whole Food Veggies capsules, and Whole Food Fiber & Spice powder products are misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] because the labels fail to identify the part of the plant (e.g., root, stalk, leaves) from which each botanical dietary ingredient in the product is derived, as required by 21 CFR 101.4(h)(1).

6. Your products Whole Food Fruits capsules, Whole Food Veggies capsules, and Whole Food Fiber & Spice powder products are misbranded within the meaning of Section 403(e)(1) of the Act [21 U.S.C. § 343 (e)(1)] in that their labels fail to list the name and place of business of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5. The street address may be omitted if it is shown in a current city directory or telephone directory.
7. Your Whole Food Fruits capsules and Whole Food Veggies capsules products are misbranded within the meaning of 403(s)(2)(B) of the Act [21 U.S.C. § 343(s)(2)(B)] because the labels do not include a statement of identity as a “dietary supplement” as required by 21 CFR 101.3(g).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct all the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation, such as photographs, corrective actions taken to date, or other useful information that would assist us in evaluating your corrections. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the corrections.

Further, 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 re-inspection-related costs. A re-inspection 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 determine whether compliance has been achieved. Re-inspection-related costs mean all expenses, including administrative expenses, incurred in connection with FDA’s arranging, conducting, and evaluating the results of the inspection and assessing and collecting the inspection fees, 21 U.S.C. § 379j-31(a)(2)(B). For a domestic facility, FDA will assess and collect fees for re-inspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

Your reply should be addressed to the U.S. Food and Drug Administration; Attn: Nancy G. Schmidt, Compliance Officer; 6th Ave. and Kipling St., P.O. Box 25087, Denver, Colorado, 80225-0087. You may reach Ms. Schmidt at (303) 236-3046 if you have any questions about this matter.

Sincerely,

/S/

LaTonya M. Mitchell, PhD.

Denver District Director

Program Division Director

Office of Human and Animal Food Operations –

Division IV West

