Herbal Junction 3/11/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
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March 11, 2016

VIA CERTIFIED MAIL
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 16-09

Jerry L. Smith, Owner
Herbal Junction
PO Box 50041
Eugene, Oregon 97405

WARNING LETTER

Dear Mr. Smith:

The United States Food and Drug Administration (FDA) inspected your processing facility, located at 50 East 25th Avenue, Eugene, Oregon, from May 26 - 29, 2015, and June 4, 2015. At this facility, you manufacture herbal enzyme elixirs that you market as dietary supplements. The liquid concentrates, coolers, herbal infusions, power tonics, tinctures and bars manufactured at this facility are marketed as conventional foods.

During the inspection, we evaluated your dietary supplement manufacturing, packaging, labeling and holding operations for compliance with Title 21, Code of Federal Regulations (21 CFR), Part 111. Your dietary supplement products comprise: Herbal Enzyme Elixir Cosmic Think Drink Herbal Supplement, Herbal Enzyme Elixir Exotic Dream Herbal Supplement, Herbal Enzyme Elixir Liver Tea and Justice Herbal Supplement, Herbal Enzyme Elixir Flower Power Herbal Supplement, Herbal Enzyme Elixir Ginger Alchemy Herbal Supplement, Herbal Enzyme Elixir Mate Way Herbal Supplement, Herbal Enzyme Elixir Love Potion #9 Herbal Supplement, Herbal Enzyme Elixir Amazon

Nectar Herbal Supplement, Herbal Enzyme Elixir Around the World Herbal Supplement, Herbal Enzyme Elixir Scarlet Ambrosia Herbal Supplement, and Herbal Enzyme Elixir Velvet Vision Herbal Supplement. The inspection revealed significant violations of the dietary supplement Current Good Manufacturing Practice (CGMP) regulations (21 CFR Part 111). These violations cause your dietary supplement products to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (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 CGMP regulations for dietary supplements.

During the inspection, we also collected a sample of your Sky High Chai Organic Liquid Concentrate product. Based on your firm's practice of shipping this hermetically-sealed product in unrefrigerated conditions, combined with FDA sample results indicating product pH above 4.6 and water activity above 0.85, your Sky High Chai Organic Liquid Concentrate is a low-acid food product, as defined by 21 CFR 113.3(n). The inspection revealed serious violations of the low-acid foods regulation (21 CFR Parts 108 and 113). These violations cause your low-acid food product to be adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. § 342(a)(4)], in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

Additionally, based on our review of product labels collected during the inspection, several of your products are misbranded under section 403 of the Act [21 U.S.C. § 343], as explained further below.

We received two e-mails from you on June 18, 2015, and June 19, 2015, concerning the observations noted on the Form FDA 483, Inspectional Observations, which was issued to your firm. We requested you submit a written response, and we subsequently received your written response to the FDA 483 on July 7, 2015. We address your response received July 7, 2015, below, in relation to the adulterated dietary supplements and adulterated low-acid food violations.

Adulterated Dietary Supplements

Our inspection revealed the following violations of the dietary supplement CGMP requirements:

1. You failed to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of your dietary supplements and that your dietary supplements are packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.70(a). Specifically, you stated during the inspection that you have not established component specifications [21 CFR 111.70(b)], in-process specifications [21 CFR 111.70(c)], finished product specifications [21 CFR 111.70(e)] or labeling and packaging specifications [21 CFR 111.70(d) and 111.70(g)] for any of your dietary supplement products. Once you have established the required specifications, you must verify that the specifications are met in accordance with 21 CFR 111.73 and 111.75, and you must make and keep records in accordance with 21 CFR 111.95(b).

Your response is inadequate as it does not address the violation of failing to establish specifications. Your response states suppliers test the herbs used as components of your dietary supplements; however, you have not identified the specifications used for such testing, nor does your response address how you intend to comply with the requirement to establish in-process specifications, finished product specifications, and labeling and packaging specifications. Your response states that you are claiming an exemption under 21 CFR 111.75(d) from finished product verification, which is the requirement to verify that finished dietary supplements meet the specifications established for them (21 CFR 111.75(c)). However, finished product verification and establishing finished product specifications are separate and different requirements. There is no exemption from the requirement to establish finished product specifications.

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). During the inspection, you stated that your firm had not prepared MMRs for your dietary supplement products.

We are unable to evaluate the adequacy of your proposed corrective actions because, although your response stated that you had prepared handwritten MMRs that would be typed and maintained digitally, you did not provide us with any of these MMRs for review, nor did you provide us with a timeline of when these MMRs will be implemented for each unique formulation and batch size of dietary supplements that you manufacture.

3. You failed to prepare a batch production record (BPR) for each batch of dietary supplements manufactured, as required by 21 CFR 111.255(a). BPRs must include complete information relating to the production and control of each batch, as required by 21 CFR 11.255(b), and all of the required elements of a batch production record as listed in 21 CFR 111.260. Our investigator found that you failed to prepare batch production records, with the exception of a log where **(b)(4)** temperatures are routinely recorded. The temperature log is inadequate in that it fails to include all elements in 21 CFR 111.260.

Your response included a copy of a spreadsheet that you indicated is being designed, which documents the batch number, date, temperature and pH. This batch record template is insufficient in that it does not include all the elements required for a BPR, as provided in 21 CFR 111.260.

4. 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 stated during the inspection that you have not established any quality control procedures.

We are unable to evaluate the adequacy of the proposed corrective actions with regard to quality control that are described in your response because you did not provide us with a copy of any written procedures for quality control operations, nor did you provide us with a timeline of when written procedures will be implemented. Further, even if you instituted the corrective actions described in your response as written procedures for quality control operations and implemented them in your facility, they would not adequately address the requirements for quality control operations in 21 CFR 111.103. For example, your proposed corrective actions do not include any procedures for making a disposition decision or approving or rejecting any processing. In addition, establishing once **(b)(4)** reviews of all manufacturing processes for your products would not meet the requirement for ensuring that all manufacturing processes meet written procedures because you must ensure that manufacturing processes are being adhered to **before** the products are shipped to customers (see 21 CFR 111.113). Further, your response says that quality control personnel will review all representative lots to ensure final products meet component specifications, but you cannot ensure component specifications have been met by testing a final product.

Guidance for small entities on how to comply with the CGMP regulations for dietary supplements is available online at **www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm**
(/Food/default.htm).

Misbranded Dietary Supplements

5. Your herbal dietary supplement products are misbranded within the meaning of section 403(y) of the Act [21 U.S.C. § 343(y)] in that the labels fail to bear a domestic street address or domestic phone number through which the responsible person (as described in section 761 of the Act [21 U.S.C. § 379aa-1]) may receive a report of a serious adverse event with such dietary supplement.

Adulterated Low-Acid Food

6. Your firm failed to register with the FDA as a commercial processor of LACF products. A commercial processor of low-acid foods in hermetically sealed containers is required, not later than 10 days after first engaging in the

manufacture, processing, and packaging of thermally processed low-acid foods in any state, as defined in section 201(a)(1) of the Act, to register and file a Form FDA 2541 (Food Canning Establishment Registration) with the FDA, as required by 21 CFR 108.35(c)(1). However, our inspection indicates that your firm processes LACF products, including but not limited to, Sky High Chai Organic Liquid Concentrate, without an LACF registration with the FDA. Your response is inadequate **(b)(3)**. LACF processors must register as commercial processors of low-acid foods, **(b)(3)**. To date, your firm has not registered with FDA as an LACF processor.

7. As a commercial processor engaged in the processing of low-acid foods packaged in hermetically sealed containers, you must, not later than 60 days after registration and prior to the packing of a new product, provide the FDA information as to the scheduled processes. This information must include the processing method, type of retort or other thermal processing equipment employed, minimal internal temperatures, times and temperatures of processing, sterilization value, or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process for each low-acid food in each container size, to comply with 21 CFR 108.35(c)(2). Specifically, your firm has failed to file a scheduled process with FDA for the Sky High Chai Organic Liquid Concentrate that your firm manufactures. Scheduled process information for LACF products must be submitted on Form FDA 2541a (Food Process Filing For All Methods Except Low-Acid Aseptic). Additional information on registration and filing can be found in the publication "Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF)," available at: **www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm (/Food/default.htm)**. Scheduled processes must be established by qualified persons having expert knowledge acquired through appropriate training and experience in the thermal processing of low-acid foods in hermetically sealed containers, as required by 21 CFR 113.83.

Your response is inadequate as it states finished product samples of Sky High Chai Organic Liquid Concentrate will be evaluated by a process authority; however, this evaluation must occur before an LACF product is processed and distributed.

Your firm is responsible for determining which regulations apply to the products that you manufacture, including whether any of these products, including liquid concentrates, are considered low-acid canned foods or acidified foods, as defined in 21 CFR 113.3(n) and 21 CFR 114.3(b), subject to the applicable provisions of 21 CFR Parts 108, 113 and 114. Accordingly, your firm should determine or have determined for you whether any additional products that you manufacture are low-acid canned foods or acidified foods, and comply with the applicable requirements of 21 CFR Parts 108, 113 and 114, including process filing, for those products that are determined to be low-acid canned foods and acidified foods.

Adulterated Conventional Foods - Unapproved Food Additives

Any substance added to a conventional food must be used in accordance with a food additive regulation, unless the substance is the subject of a prior sanction or is generally recognized as safe (GRAS) among qualified experts for its use in foods [21 CFR 170.30(g)].

Several of your liquid concentrates, coolers, herbal infusions, and bars contain substances that are food additives as defined in section 201(s) of the Act [21 U.S.C. 321(s)]. These substances include, but are not limited to, the following:

- Kava kava used in Cocoa Mystic Cacao Herbal Elixir Infusion Liquid Concentrate, Kava Chai Liquid Concentrate, Cooler Exotic Dream Herbal Enzyme Elixir, Cooler Around the World Herbal Enzyme Elixir, Euphoric Espress [sic] Herbal Infusion, Kava Chai Herbal Infusion, Mystic Wild Jun Bar, Kava Kava Pacific Herb of Peace and Spirit Up Natural Herbs of Spirit;
- Jatoba used in Mate Rainforest Chai Liquid Concentrate, Cooler Ginger Alchemy Herbal Enzyme Elixir, Cooler Cosmic Think Drink Herbal Enzyme Elixir, Blue Heaven Herbal Infusion, Epic Espress [sic] Herbal Infusion, Mate

Rainforest Chai Herbal Infusion, Cup of Health Herbal Infusion, Rainforest Energy Jun Bar, Rainforest Energy Tonic Natural Herbs of Endurance, and Extreme Energy Natural Herbs of Wake-fullness;

- Pau d'arco used in Cocoa Mystic Cacao Herbal Elixir Infusion Liquid Concentrate, Mate Rainforest Chai Liquid Concentrate, Cooler Mate Way Herbal Enzyme Elixir, Cooler Exotic Dream Herbal Enzyme Elixir, Cooler Amazon Nectar Herbal Enzyme Elixir, Cooler Around the World Herbal Enzyme Elixir, Mate Rainforest Chai Herbal Infusion, Cup of Health Herbal Infusion, Sweet Vanilla Mate Herbal Infusion, Rainforest Energy Jun Bar, Immune Solution Jun Bar, Mystic Wild Jun Bar and Spirit Up Natural Herbs of Spirit; and
- Ginkgo used in Cooler Mate Way Herbal Enzyme Elixir and Cooler Cosmic Think Drink Herbal Enzyme Elixir.

There is no food additive regulation which authorizes the use of kava kava, jatoba, pau d'arco or ginkgo. We are not aware of any information to indicate these substances are the subject of a prior sanction [see 21 CFR 181]. As explained below, we are not aware of any basis to conclude that these substances are GRAS for use in conventional foods.

FDA's regulations in 21 CFR 170.30(a)-(c) describe criteria for eligibility for classification of a food ingredient as GRAS. General recognition of safety must be based only on the view of qualified experts. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. In addition, general recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

- Under 21 CFR 170.3(h), "[s]cientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance." Under 21 CFR 170.30(b), "[g]eneral recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient." Section 170.30(b) further states that general recognition of safety through scientific procedures is ordinarily based upon published studies, which may be corroborated by unpublished studies and other data and information.
- Under 21 CFR 170.3(f), "[c]ommon use in food means a substantial history of consumption of a substance for food use by a significant number of consumers." Under 21 CFR 170.30(c)(1), "[g]eneral recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information." Importantly, however, the fact that a substance was added to food before 1958 does not, in itself, demonstrate that such use is safe, unless the pre-1958 use is sufficient to demonstrate to qualified experts that the substance is safe when added to food [21 CFR 170.30(a)].
- Under 21 CFR 170.3(i), "[s]afe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." The regulation provides that, in determining safety, the following factors are to be considered: (1) The probable consumption of the substance and of any substance formed in or on food because of its use; (2) the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet; and, (3) safety factors which, in the opinion of qualified experts, are generally recognized as appropriate. Such safety factors ordinarily are established through extensive testing in animals to determine whether consumption of the ingredient produces adverse effects when consumed chronically (i.e., on a daily basis over the course of a lifetime).

We know of no basis for general recognition of safety for kava kava, jatoba, pau d'arco and ginkgo based either on scientific procedures or common use in food prior to January 1, 1958. In assessing the GRAS status of these substances for use in conventional foods such as yours, we considered the criteria described above. FDA is not aware of data to establish the general recognition of safety of these substances for use as an ingredient in

conventional foods. Therefore, the use of these substances in your liquid concentrate, coolers, herbal infusion and bar products does not satisfy the criteria for GRAS status under 21 CFR 170.30.

8. FDA is not aware of any other exemption from the food additive definition that would apply to kava kava, jatoba, pau d'arco and ginkgo for use as ingredients in a conventional food. Therefore, these substances added to a conventional food are food additives under section 201(s) of the Act [21 U.S.C. § 321(s)] and are subject to the provisions of section 409 of the Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. Kava kava, jatoba, pau d'arco and ginkgo are not approved for use in any conventional food. Therefore, your liquid concentrates, coolers, herbal infusions and bars which contain kava kava, jatoba, pau d'arco and ginkgo are adulterated within the meaning of section 402(a)(2)(C) of the Act. These adulterated liquid concentrate products include Cocoa Mystic Cacao, Mate Rainforest Chai and Kava Chai varieties; cooler products include Mate Way, Exotic Dream, Ginger Alchemy, Amazon Nectar, Around the World and Cosmic Think Drink varieties; herbal infusions include Euphoric Espress [sic], Kava Chai, Blue Heaven, Epic Espress [sic], Mate Rainforest Chai, Cup of Health and Sweet Vanilla Mate varieties; and bars include Rainforest Energy Jun, Immune Solution Jun and Mystic Wild Jun varieties.

Misbranded Conventional Foods

9. Your Ginseng Journey Espress [sic] herbal infusion, Immune Solution Jun bar and Spirit Up tincture products are misbranded within the meaning of section 403(u) of the Act [21 U.S.C. § 343(u)] in that they purport to contain ginseng, but the purported ginseng ingredient is not from a plant classified within the genus Panax. Section 403(u) of the Act, added by the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171), provides that the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus Panax. Your Ginseng Journey Espress [sic] herbal infusion, Immune Solution Jun bar and Spirit Up tincture products contain an ingredient identified as Siberian Ginseng (*Eleutherococcus senticosus*). That ingredient may not be declared under a name that includes the term "ginseng" because it is not from the genus Panax. Although we did not review every product label or attempt to identify every misbranding violation, we noted that a number of your other product labels refer to ingredients that do not appear to be from the Panax genus as "ginseng." You should review all of your product labels to ensure that the term "ginseng" is not used in a way that misbrands the product.

10. Your Immune Solution Jun Bar and Field Trip Herbal Infusion are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that these products are fabricated from two or more ingredients, but their labels fail to bear the common or usual name of each ingredient in the product as required by 21 CFR 101.4(a)(1). Specifically, the ingredient statement for the Immune Solution Jun Bar declares "Jun culture" and "sucanat," which are not common or usual names of ingredients. Your ingredient statement must declare these ingredients by common or usual names that accurately identify or describe their basic nature or characterizing properties or ingredients (21 CFR 102.5) (e.g., for a culture, "bacteria and yeast culture" or "bacteria and mold culture"). "Jun culture" does not meet this requirement because it provides no information about the nature, properties, or ingredients of the culture. Similarly, "Sucanat" is a trade name used for marketing purposes, not a common or usual name that identifies or describes the basic nature or properties of the ingredient.

11. Your Cosmic Think Drink Herbal Enzyme Elixir product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that it is a food which purports to be a beverage containing fruit or vegetable juice but the label fails to bear a statement on the information panel of the total percentage of such fruit or vegetable juice contained in the food [21 CFR 101.30(a)].

12. Your Field Trip Herbal Infusion product is misbranded within the meaning of section 403(e)(1) of the Act [21 U.S.C. § 343(e)(1)] in that the place of business of the manufacturer, packer, or distributor is not declared in accordance with 21 CFR 101.5. Specifically, the street address, city, state and zip are omitted from the label.

13. Your Cosmic Think Drink and Immune Solution Jun Bars are misbranded within the meaning of section 403(q) of the Act [21 U.S.C. § 343(q)] in that the label does not include a Nutrition Facts panel as required by 21 CFR 101.9.

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of labeling violations. Other labeling violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

(b)(3)

This letter may not list all the violations at your facility. 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. You are also responsible for ensuring that your processing plant operates in compliance with the Act, the CGMP dietary supplement regulation (21 CFR Part 111), the low-acid foods regulation (21 CFR Parts 108 and 113) and the food labeling regulation (21 CFR Part 101), and any other regulations that apply.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product, enjoin your firm from operating, and/or issue an Order of Need to obtain and hold a Temporary Emergency Permit.

We have the following comments regarding the labeling of your conventional food products:

- For your Ginseng Journey Espress [sic] Herbal Infusion product, if “Prince Ginseng” is not from the genus Panax, it may not be declared under any name that includes “ginseng.”
- Your Cosmic Think Drink Herbal Enzyme Elixir, Ginseng Journey Espress [sic] Herbal Infusion, Immune Solution Jun Bar, and Spirit Up tincture products do not list the street address of your place of business. The statement of the place of business shall include the street address, city, state, and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory [21 CFR 101.5(d)].
- The ingredient statement for your Immune Solution Jun Bar product is not in the correct format. Currently, the product label contains two lists of ingredients, one for the entire bar and the other for the “Immune Solution” component of the bar. Because “Immune Solution” does not have an established common or usual name, it should not be listed as an ingredient of the bar (see 21 CFR 101.4(b)(2)). Rather, there should be only one ingredient statement on the product label and it should list all ingredients in the bar, including those that are components of “Immune Solution,” by common or usual name in descending order of predominance by weight in the finished product (the bar) (see 21 CFR 101.4(a)).
- We note that your Immune Solution Jun Bar ingredient statement declares “lecithin” as an ingredient. If this ingredient is from egg or soy, the ingredient statement does not meet the requirements of section 403(w)(1) of the Act, which states that specified allergens must be declared in the ingredient statement or in a “Contains” statement that immediately follows the ingredient statement.
- Your Field Trip Herbal Fusion Infusion product declares “stevia” in its ingredient list, but it is not clear from the ingredient list whether you are using stevia leaves, a crude stevia extract, or a purified extract in this product. If you are using stevia leaves or crude extracts obtained from stevia leaves in Field Trip Herbal Fusion Infusion or other conventional foods you produce, be advised that FDA considers these substances to be unsafe food additives when used in conventional foods (see FDA Import Alert 45-06, “Detention without Physical Examination of Stevia Leaves, Crude Extracts of Stevia Leaves and Foods Containing Stevia Leaves and/or Stevia Extracts,”