Lopez Gonzalez Santana Corporation dba Domel and dba Dermixx 8/28/17

Office of Human and Animal Food Operations
East Division IV
Compliance Branch
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August 28, 2017

WARNING LETTER

17-OHAFOE4-WL-09 / CMS No. 524175

VIA UNITED PARCEL SERVICE
NEXT DAY – SIGNATURE REQUIRED

Mr. Jaime Gonzalez Castrodad, President
Lopez Gonzalez Santana Corporation (dba Domel and dba Dermixx)
488 (Altos) Calle de Diego
Rio Piedras, Puerto Rico 00924

Dear Mr. Gonzalez Castrodad:

During our January 31 through February 10, 2017, inspection of your firm located at Calle de Diego #488, Rio Piedras, PR 00924, an investigator from the Food and Drug Administration (FDA) identified significant violations of Current Good Manufacturing Practice (CGMP) regulations for Dietary Supplements, Title 21, Code of Federal Regulations, Part 111. These CGMP violations cause your dietary supplement product(s) Hydrazone, ALZ, Calci-Max, Daflonex, Enzycap, Iro-Plex liquid, Iro-Plex caplets, Skelagesic, Stonex, Maltaglobin, Transferon, and Collagen Capsules 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)] because they have been prepared, packed or held under conditions that do not meet CGMP requirements for dietary supplements. In addition, we have reviewed the labeling for your ALZ, Calci-Max and Iro–Plex Liquid dietary supplements and determined that it is misbranded within the meaning of Section 403 of the Act [21 U.S.C. § 343]. You can find the Act and FDA regulations through links in FDA's website at **www.fda.gov (http://www.fda.gov/)**.

At the conclusion of the inspection on February 10, 2017, your firm was issued a Form FDA 483, Inspectional Observation. We acknowledge receipt of your response, dated February 16, 2017, and noted that the response lacks sufficient information regarding the proposed corrective actions.

Specific violations observed during the inspection include, but are not limited to, the following:

Adulterated Dietary Supplements

1. 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, as required by 21 CFR 111.103. Specifically, you had no written procedures for the responsibilities of the quality control operations. Once you have established your procedure(s), you must implement it in accordance with 21 CFR 111.65 to ensure the quality of the dietary supplement.

You receive finished, packaged and labeled dietary supplements from a manufacturer that manufactures the dietary supplements on your behalf (your contract manufacturer). You hold and distribute the dietary supplements. You state that you developed the formulation for your products, and that you provide your contract manufacturer with the particular product formula including container/closure system (such as container type, size, and quantity of product), based on collaboration with your contract manufacturer.

As a distributor that contracts with a manufacturer to manufacture, package, and label dietary supplements on your behalf that your firm releases for distribution under your firm's name, you have an obligation to know what and how manufacturing activities are performed. This is so that your firm can make decisions related to whether the packaged and labeled dietary supplement products conform to established specifications and whether to approve and release the products for distribution [See 72 Fed. Reg. 34752, 34790 (June 25, 2007)]. Your firm's quality control personnel must ensure that the manufacturing, packaging, labeling, and holding operations ensure the quality of your dietary supplements and that the dietary supplements are packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.105. Further, you must have documentation of the quality control personnel review and approval for release of any packaged and labeled dietary supplement (21 CFR 111.127(h) and 21 CFR 111.140(b)(2)).

We have reviewed your response dated February 16, 2017. You state that you visit the manufacturing facilities and evaluate them using a questionnaire identified as FMQE 1022-Supplier Quality Evaluation Questionnaire. Your response does not address your firm's corrective actions in establishing written procedures which describe the responsibilities of your quality control unit.

2. 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, as required by 21 CFR 111.70(e). Specifically, during the inspection you stated that you have not developed and implemented specifications for your finished dietary supplement products.

We have reviewed your response dated February 16, 2017. You state that you will request that all manufacturing firms attach a Certificate of Analysis (COA) to the commercial invoice of each product; however, no documentation of the established finished product specifications were provided for your dietary supplements. Therefore, we are unable to evaluate the adequacy of your response.

3. You failed to establish and follow written procedures for how you review and investigate product complaints, as required by 21 CFR 111.553. Your written procedure must fulfill the requirements of 21 CFR 111.560 and you must make and keep records in accordance with 21 CFR 111.570. Specifically, during the inspection it was observed by

our investigator that you do not have a written procedure detailing the steps to be taken in response to product complaints.

4. You failed to establish and follow written procedures to fulfill the requirements for returned dietary supplements, as required by 21 CFR 111.503. Specifically, you informed our investigator that you did not have written procedures for returned dietary supplements.

We also have the following comment:

- Your response letter dated February 16, 2017, states that you will retain two containers of each new product lot received and will store them in the warehouse in the area designated as “Sample of Packages Products.” The containers will be kept until they reach the expiration date. Additionally, you will also keep label specimens of the products at the facility. This corrective action has not met the requirements of 21 CFR 111.83(b)(3).

Misbranded Dietary Supplements

1. Your ALZ and Iro-Plex Liquid dietary supplements products are misbranded within the meaning of 403(s)(2)(B) of the Act [21 U.S.C. § 343(s)(2)(B)] in that the label fails to identify the product by using the term “dietary supplement” as a part of the product’s statement of identity, as required by 21 CFR 101.3(g), except that the word "dietary" may be deleted and replaced by the name of the dietary ingredients in the product or an appropriately descriptive term indicating the type of dietary ingredients that are in the product.

2. Your Calci-Max and Iro-Plex Liquid products are misbranded within the meaning of section 403(q)(1)(A) of the Act [21 U.S.C. §§ 343(q)(1)(A)] because the serving size declared on each label is incorrect. Serving size for a dietary supplement is the maximum amount consumed per eating occasion as recommended on the product label as defined in 21 CFR 101.9(b) and 21 CFR 101.12(b) Table 2. For example:

- The Calci-Max directions of use suggest the consumer take one (1) or two (2) capsules daily, but the serving size lists 1 capsule. The serving size listed should be two capsules.
- The Iro-Plex Liquid serving size is not expressed in a common household measure. The directions of use suggest the consumer take a teaspoon (5ml) daily, but the serving size lists 5 ml. The serving size listed should be 1 teaspoon (5 ml).

3. Your Iro-Plex Liquid product label is misbranded within the meaning of Section 403(e)(1) of the Act [21 U.S.C. § 343 (e)(1)] in that it fails to list the name and place of business of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5.

4. Your Calci-Max product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that the product label fails to declare the common or usual names of each ingredient used as required by 21 CFR 101.36 and 21 CFR 101.4. For example, the label declares the ingredient K-2 (Menatetrenone), but this is not the common or usual name for vitamin K.

5. Your Iro-Plex Liquid product is misbranded within the meaning of Section 403(q)(1)(B) of the Act [21 U.S.C. § 343(q)(1)(B)] because it fails to declare the correct number of servings per container in accordance with 21 CFR 101.36(b)(1)(ii). The net weight (118 ml) divided by the serving size (5 ml) results in about 23 servings, but the label lists the servings per container as “about 6.” The servings per container should be listed as “about 23.”

6. Your ALZ, Iro-Plex Liquid, and Calci-Max 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 labeling of your product does not comply with 21 CFR 101.36. For example:

- Your ALZ product label lists a %DV for N Acetyl Cisteine, but a Daily Value has not been established for that dietary ingredient.
- Your Iro-Plex Liquid product label declares incorrect %DV's for iron and vitamin B-6 based on the amount per serving declared.
- Your Calci-Max product label fails to declare the %DV for zinc, magnesium, and selenium.
- Your Iro-Plex Liquid and Calci-Max product labels fail to list the dietary ingredients in the correct order in accordance with 21 CFR 101.36(b)(2)(i)(B) and 101.36(b)(3)(i).
- Your Iro-Plex Liquid and Calci-Max product labels fail to present the nutrition information in the correct format in accordance with 21 CFR 101.36(e), in that a heavy bar shall separate the (b)(2)- and (b)(3)-dietary ingredients, with the latter presented below the heavy bar.
- Your Iro-Plex Liquid product label fails to use the correct unit of measurement on the quantitative amount declared for vitamin B-12 and folic acid, and your Calci-Max product fails to use the correct unit for folate and selenium, in accordance with 21 CFR 101.9(c)(8) and 101.36(b)(2)(ii)(B).

7. Your Iro-Plex Liquid product is misbranded within the meaning of section 403(r)(1)(A) of the Act, 21 U.S.C. § 343(r)(1)(A), because its label contains a nutrient content claim that does not comply with 21 CFR 101.60(c). The product label bears the claim "sugar free" but fails to meet the requirements to bear that claim, because corn syrup is listed first under Other ingredients.

8. Your Calci-Max product is misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] because the label fails to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the product is derived, as required by 21 CFR 101.4(h)(1).

We also have the following comments:

- Your ALZ product label, it appears the dietary ingredient vinpocetine is misspelled as vipocesetin and huperzine is misspelled as hupersine. Your Calci-Max product label misspells the following terms: zinc chelate, selenium, and Rhodiola.
- Your Iro-Plex Liquid product declares the ingredient "butterscotch flavor" but fails to specify if the flavor is artificial or natural.
- Your Iro-Plex Liquid product label notes "Daily Value not established" but does not include a column for % Daily Value and does not include an "*" to designate that the Daily Value has not been established for the dietary ingredient. Your Calci-Max product does not indicate "Daily Value not established" for flaxseed oil cold pressed, black cohosh extract, or Rhodiola rosea extract.
- Your Calci-Max product declares the term "Lifenol," which is not a common or usual name of an ingredient. Furthermore, it appears by the listing of "Lifenol & Humulus lupulus" that these terms may be two separate ingredients. If this is not the case, then the names "Lifenol" and "Humulus lupulus" should be listed in such a way that the consumer is aware of the relationship between the "Lifenol" and the "Humulus lupulus."
- Your Calci-Max product label claims "L-methylfolate" on the primary display panel, but the Supplement Facts label declares "methylfolate."

This letter may not list all the violations at your facility or that exist in connection with your products or their labeling. You are responsible for ensuring that your products are in compliance with the Act and all applicable FDA regulations, including the CGMP regulation for dietary supplements. You should take prompt action to correct the violations cited in this letter and prevent their recurrence. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.