Vicare International (USA) INC 9/11/17

U.S. FOOD & DRUG ADMINISTRATION

Los Angeles District
19701 Fairchild, Irvine CA 92612-2506
Telephone: 949-608-2900

WARNING LETTER

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

September 11, 2017

WL# 522768-17

Ling-Li (Lily) Liu, Owner/President
Vicare International (USA), Inc.
1041 S. Garfield Ave., Ste. 211
Alhambra, CA 91801-4765

Dear Ms. Liu:

The United States Food and Drug Administration (FDA) inspected your facility located at 1041 S. Garfield Ave., Stes. 205 and 211, Alhambra, California, from February 22, 2017 through March 1, 2017. The inspection revealed serious violations of the FDA's regulations for Current Good Manufacturing Practice (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, under Title 21, Code of Federal Regulations (CFR), Part 111 (21 CFR Part 111). These violations cause the 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 CGMP requirements for dietary supplements.

We have received your written response dated March 17, 2017, concerning our investigator's observations noted on the FDA-483, Inspectional Observations, which was issued to you on March 1, 2017. Our comments regarding the adequacy of the actions you took to correct the objectionable conditions and practices observed during the inspection are detailed after the applicable violations, noted below.

The significant violations documented during the inspection include, but are not limited to, the following:

Adulterated Dietary Supplements

As a distributor that contracts with other manufacturers to manufacture, package, or label dietary supplements that your firm releases for distribution under your firm's name, your firm has an obligation to know what and how manufacturing 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.

Although your firm may contract out certain dietary supplement manufacturing operations, it cannot by the same token, 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 (1983) (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), 331(a)). Thus a firm that contracts with other firms to conduct certain dietary supplement manufacturing, packaging, and labeling operations is responsible for ensuring that the dietary supplement is not adulterated for failure to comply with dietary supplement CGMP requirements, regardless of who actually performs the dietary supplement CGMP operations.

The inspection revealed the following significant violations of the CGMP requirements for dietary supplements. These violations cause your dietary supplement products to be adulterated under 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 which do not meet the CGMP regulations for dietary supplements.

1. You failed to establish specifications for each dietary supplement for the identity and strength of the finished batch of the dietary supplement to ensure the quality 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 dietary supplement, as required by 21 CFR 111.70(e).

We note that you develop product formulas and that you provide the contract manufacturer with finished product specifications. We have reviewed your response dated March 17, 2017, and determined your response to be inadequate. Your response letter provides specification sheets for your "VI – DiabeCare," "VI – Prosta Care," "VI – Sheep Placenta," "VI – Vessel Care II," "VI – LiverCare" products and "Nu – DiabeCare," "Nu – Sheep Placenta," "Nu – Prosta Care," "Nu – Angio Care," "Nu – LiverCare" products. Your product specification sheets are inadequate because they do not include adequate acceptance criteria for the identity of the finished products. For example, your specification sheet for "VI-DiabeCare" lists **(b)(4)** and **(b)(4)** as identity criteria. However, it is not possible to verify the identity or the purity, strength, composition, and absence of contaminants that may adulterate your product by **(b)(4)**. Further, your finished product specifications do not list the method of strength testing of each dietary ingredient.

In addition, in your response dated March 17, 2017, you did not provide revised finished product specifications for the following three products:

- "Vicare Vi-Reishi"
- "NuLife Nu-Reishi"
- "Vicare Super Cell"

2. You failed to establish specifications for your dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications), as required by 21 CFR 111.70(d). As was discussed during the inspection, your firm **(b)(4)**, **(b)(4)**, and **(b)(4)** and **(b)(4)** to your contract manufacturer. Once you have established label and packaging specifications, your quality control personnel must ensure packaging and labels conform to established specifications, in accordance with 21 CFR 111.120(b).

We are unable to evaluate the adequacy of your response dated March 17, 2017, because you did not provide label and packaging specifications for some of your products. For example, you did not provide label and packaging specifications for the following products:

- "Vicare Vi-Reishi"
- "NuLife Nu-Reishi"
- "Vicare Super Cell"

(b)(4)

This letter is not intended to be an all-inclusive list of violations at your facility or in connection with your products. You are responsible for ensuring that your facility operates in compliance with the Act and other applicable laws.

You should take prompt action to correct the violations noted in this letter. Failure to do so may result in regulatory action by FDA without further notice, including, without limitation, seizure and injunction.

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 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 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.

You should respond in writing within 15 working days of receipt of this letter describing the specific steps you have taken to correct the noted violations and to prevent these violations or other similar violations from occurring again. In your response, you should include documentation, including photographs, corrective actions you have taken to date, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should state the reason for the delay and include a timetable for implementation of those corrections.

Your written response should be directed to:

Matthew Walburger, Acting Director Compliance Branch
Food and Drug Administration
HAF Division West 5
19701 Fairchild

Irvine CA 92612-2506

Refer to the Unique Identification Number (CMS #522768) when replying.

If you have questions regarding this letter, please contact Rochelle A. Rolnik, Compliance Officer at **rochelle.rolnik@fda.hhs.gov (mailto:rochelle.rolnik@fda.hhs.gov)** , or (949) 608-4496.

Sincerely,
/S/
Jeanmaire Hryshko
for
Darla Bracy, Division Director
Office of Human and Animal Foods
Division 5 West
US Food and Drug Administration

cc:
David Mazerra, Ph.D.
Chief, Food and Drug Branch
California Department of Public Health
1500 Capitol Avenue - MS 7602
P.O. Box 997413
Sacramento, California 95899-7435

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)