U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Seattle District Office
22215 26th Avenue SE,
Suite 210
Bothell, Washington 98021

May 12, 2017

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to WL SEA 17-14

Otto Roder, President
VitaPurity Corporation
5246 Dobrot Way
Central Point, Oregon 97502

WARNING LETTER

Dear Mr. Roder:

The United States Food and Drug Administration (FDA) conducted an inspection of your facility, located at 5246 Dobrot Way, Central Point, Oregon, from November 1, 2016, through November 4, 2016. During our inspection, you informed our investigator that your firm holds and distributes dietary supplements that your contract manufacturer manufactures, packages, and labels under your own firm's name. We found serious violations of the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements regulation, Title 21, Code of Federal Regulations (CFR), Part 111 (21 CFR Part 111). These violations cause your dietary supplement products Ellagic Ultra, Buffered Vitamin C Crystals, Coral Calcium with D3, Miracle Mushroom Blend, Lycopene 25 with Tomato Powder, Citral from Lemon Grass, and Pacific Ocean Shark Cartilage 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 the dietary supplements have been prepared, packed, or held under conditions that do not meet CGMP requirements for dietary supplements.

We collected product labels during the inspection for products you hold and distribute under your firm's name, including Ellagic Ultra, Buffered Vitamin C Crystals, Coral

Calcium with D3, Miracle Mushroom Blend, Lycopene 25 with Tomato Powder, Citral from Lemon Grass, and Pacific Ocean Shark Cartilage. In addition, FDA reviewed labeling on your website http://vitapurity.com. Based on our review, we have concluded that your products identified below are in violation of sections 502(f)(1) and/or 505(a) of the Act [21 U.S.C. §§ 352(f)(1) and/or 355(a)]. You may find the Act and FDA regulations through links on the FDA's home page at www.fda.gov.

Unapproved New Drugs/Misbranded Drugs

The FDA reviewed your website http://vitapurity.com in April 2017 and determined that you take orders there for the products Ellagic Ultra, Buffered Vitamin C Crystals, Coral Calcium with D3, Miracle Mushroom Blend, Lycopene 25 with Tomato Powder, Citral from Lemon Grass, and Pacific Ocean Shark Cartilage. In addition, FDA reviewed your product labels. The claims on your product labels and website establish that these products are drugs under section 201(g)(1)(B) of 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 claims that provide evidence that your products are intended for use as drugs include:

Ellagic Ultra

Website:

- "The American Cancer Society wrote that Ellagic Acid may, 'reduce…birth defects … and promote wound healing'… They also pointed out that studies demonstrated Ellagic Acid inhibited {dangerous} cell growth and helped reduce the risk of chromosome damage."
- "Ellagic acid exhibits the ability to stop both {life-threatening} cellular changes and {malevolent} cellular mutations in humans."
- "VitaPurity Ellagic Ultra contains Green tea catechin extract…Green tea has been shown to …inhibit abnormal blood clot formation."
- "New studies suggest that Green tea may be especially protective against harmful {mutagenic} cells in the lungs of former and current cigarette smokers."

Your website also includes disease claims in the form of citations to publications or references. When scientific publications or references are used commercially by the seller of a product to promote the product to consumers, such references may become evidence of the product's intended use. For example, under 21 CFR 101.93(g)(2)(iv)(C), a citation of a publication or reference in the labeling of a product is considered to be a claim about disease treatment or prevention if the citation refers to a disease use and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease. The following are examples of citations on your

website used to market Ellagic Ultra for disease treatment and prevention and are thus evidence of your product's intended use as a drug:

- Harris, G.K., G.D. Stoner and S.J. Schwartz. 2000. Effects of freeze dried raspberries on ayoxymethane induced colon tumors in the F344 rat. OARDC poster session (unpublished)
- Stoner, G.D. and H. Mukhtar. 1995. Polyphenols as cancer chemo-preventive agents. J. of Cellular Biochemistry, Supplement 22:169-180.
- Nepka, C., E. Asprodin and D. Koretsas. 1999. Tannins, xenobiotic metabolism and cancer chemoprevention in experimental animals. Eur. J. Drug Metab. Pharmacokinet., 24(2): 183-9.
- Khanduja, K.L., et al., 1999. Prevention of N-nitrosodiethylamine-induced lung tumorigenesis by ellagic acid and quercetin in mice. Food Chem. Toxicol., 37(4):313-8.

Product Label:

- "Inhibits blood clot formation"

Buffered Vitamin C Crystals

Website:

- "The Japanese College of Intravenous Therapy stated that, 'People living in the affected areas should regularly take…vitamin C to counteract the negative consequences of long-term low dose radiation exposure…'"
- "VitaPurity Also Offers Help Against the Flu"
- "[R]ecommended VitaPurity Buffered Vitamin C Crystals as an important supplement to include with other antiviral medications."
- "Vitamin C is essential in healing scrapes, bumps & bruises…Vitamin C feeds the body's production of antibodies…"
- "[S]ufficient evidence exists to support the testing of intravenous Vitamin C for extended periods as a cytotoxic therapy agent, in doses high enough to maintain plasma levels sufficient to destroy {life-threatening} cells in the laboratory."
- "A significant percent of the 'terminally ill'…patients for whom death was considered inevitable within a matter of weeks or months went on to long term survival…"

Coral Calcium with D3

Website:

- "[I]ncreasing calcium intake can help maintain normal blood pressure in pregnant women. Pregnancy-induced high blood pressure is a serious complication that can put both mother and child at risk."
- "Additional calcium intake may actually lower your risk for kidney stones."

Your website also includes disease claims in the form of citations to scientific publications. As explained above, when scientific publications or references are used commercially by the seller of a product to promote the product to consumers, such references may become evidence of the product's intended use as a drug. For example:

- Bucher, H.C., et al., Effect of Calcium Supplementation on Pregnancy-Induced Hypertension and Preeclampsia: A Meta-analysis of Randomized Controlled Trials, Journal of the American Medical Association, 275:14, 1996.
- Sakhaee, K., et al., Limited Risk of Kidney Stone Formation During Long-Term Calcium Citrate Supplementation in Nonstone Forming Subjects, Journal of Urology, 152:324-327, 1994.

Miracle Mushroom Blend

Website:

- "Reishi Mushroom was comparable to hydrocortisone and aspirin in its ability to reduce inflammation when both taken orally and applied directly to the skin."
- "'When more than 2,000 patients with chronic bronchitis were given Reishi Mushroom Extract, 60 to 90 percent of these patients actually felt better, including increased appetite…'"
- "These mushrooms are also said to help reduce the risk of heart trouble by producing interferon to fight infections (a group of natural proteins that inhibits viruses from multiplying)."
- "Research in Japan shows that the mushroom itself can actually lower blood pressure"
- "[G]iving Shiitake to patients with severely compromised immune systems… improved their immune status."
- "People with Type 2 Diabetes may also benefit from Maitake."

Product Label:

- "Helps lower blood pressure and cholesterol."

Lycopene 25 with Tomato Powder

Website:

- "[D]iets rich in tomatoes and tomato products significantly reduced the risk of developing {an unhealthy prostate}. Lycopene was the only carotenoid associated with the lower risk."
- "Lycopene was the only carotenoid that appeared to reduce the risk of heart trouble."

Product Label:

- “Even protects skin from sunburn”

Citral from Lemon Grass

Website:

- “[T]he discovery of it’s [sic] effectiveness against {dangerous altered} cells is a relatively new development.”
- “While the Citral killed the {invading} cells…”
- “Combats occasional depression”
- “Used to ease the symptoms associated with fever, coughs, sneezing, runny nose…”
- “[R]ecommended to help relieve the symptoms of painful and difficult menstruation”

Product Label:

- “Used for hundreds of years to help lift depression...”
- “Helps reduce fever by lowering body temperature.”
- “Helps ease symptoms of painful and difficult menstruation.”

Pacific Ocean Shark Cartilage

Website:

- “Shark cartilage has been successfully used in humans to reduce pain in bones and joints and to improve mobility.”
- “[S]hark cartilage contains an angiogenesis inhibiting substance that strongly inhibits the growth of new blood vessels that support {harmful cells}, thereby restricting {their} growth.”

Product Label:

- “Helps reduce pain in bones and joints and improves mobility.”
- “Mucopolysaccharides reduce inflammation…”

Your products listed above are not generally recognized as safe and effective for the above referenced uses and, therefore, they 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. §§ 321(d) and 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.

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 Miracle Mushroom Blend and Citral from Lemon Grass 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, Miracle Mushroom Blend and Citral from Lemon Grass fail to bear adequate directions for their intended use and, therefore, these 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)].

Dietary Supplement CGMP Violations

Even if your product labeling did not contain claims that render the products unapproved and misbranded drugs, our investigator observed the following violations of the FDA's Current Good Manufacturing Practice (CGMP) requirements for dietary supplements, Title 21, Code of Federal Regulations (CFR), Part 111 (21 CFR Part 111), which would render your products adulterated dietary supplements under section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] for the reasons described below.

1. You failed to 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). Specifically, you had no 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, and no written procedures for approving for release, or rejecting, any packaged and labeled dietary supplement (including a repackaged or relabeled dietary supplement) for distribution, as required by 21 CFR 111.127(h).

   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 specify the active ingredients and their proportions for each of your products. You design and approve the product labels and have them printed and shipped to your contract manufacturer. You sometimes procure dietary ingredients and supply them to your contract manufacturer. You state that you assume your contract manufacturer is responsible for preparing a master manufacturing record, exercising quality control functions, and verifying that the finished products meet specifications. You state that you assume your contract

manufacturer is complying with 21 CFR Part 111 because you are unaware of any problems at the plant. You state that you do not have a written agreement with your contract manufacturer, and have not performed any audit or engaged in any other activity to determine the acceptability of the manufacturer to manufacture your dietary supplement products, or to ensure the quality of the dietary supplements received and that the products are packaged and labeled as specified in the master manufacturing record.

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, 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)]. Although a firm may contract out certain dietary supplement manufacturing, packaging, and/or labeling 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. [1] 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). 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 111.140(b)(2)).

This letter is not an all-inclusive list of violations at your facility. It is your responsibility to ensure that your products comply with the Act and FDA's implementing regulations. Failure to promptly correct the violations specified above may result in enforcement action without further notice, including seizure of violative products and/or injunction. In addition to the violations described above, we have the following comment:

You showed our investigator a product complaint form that you prepared as a result of a previous inspection. Please note that in addition to having a written record of product complaints, you must establish written procedures to fulfill the other requirements related to product complaints, as required by 21 CFR 111.553. Also, you must have written procedures for returned dietary supplements, as required by 21 CFR 111.503.

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 non-compliance 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 non-compliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

Please notify this office in writing within fifteen (15) business days from your receipt of this letter of the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, state the reason for the delay and the date by which you will complete the corrections.

Please send your reply to the Food and Drug Administration, Seattle District Office, 22215 26th Avenue SE, Suite 210, Bothell, Washington, 98021, to the attention of Jessica L. Kocian, Compliance Officer. If you have any questions concerning this letter, you can contact Compliance Officer Jessica Kocian at (425) 302-0444.

Sincerely,
/s/
Miriam R. Burbach
District Director

cc: Oregon Department of Agriculture
Food Safety Division
635 Capitol Street NE
Salem, Oregon 97301

[1] 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).