FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
SEATTLE DISTRICT OFFICE (SEA-DO)

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

June 30, 2017

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

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

Dear Mr. Roder:

We received your letter dated May 26, 2017, written in response to Warning Letter SEA 17-14, dated May 12, 2017.

We have reviewed your response and your website http://vitapurity.com and have determined your response is inadequate to address the violations listed in the Warning Letter. We provide additional comments below to address your statements in your response.

In regard to the unapproved new drugs/misbranded drugs, we reviewed your website http://vitapurity.com on June 6, 2017, and observed that all claims listed in the Warning Letter as establishing your products as drugs because of their intended use in the cure, mitigation, treatment or prevention of disease remain on your website. Additionally, your response did not indicate whether you have corrected any of the product labels that are placed directly on the product and for which claims were also listed in the Warning Letter. You have made no corrections in response to the receipt of the Warning Letter and therefore your response is inadequate.

Your response disagrees with FDA's determination of your products as unapproved new drugs and misbranded drugs. You assert that you are complying with FDA regulations and guidance regarding structure/function claims and provide your rationale for why some of the claims listed in the Warning Letter do not cause your products to be drugs. As you acknowledge, this Warning Letter is not the first communication you have received from FDA regarding disease claims made about your products. Your firm was previously issued two Warning Letters, participated in a teleconference meeting with FDA Seattle District Office and FDA Center for Food Safety and Applied Nutrition, and received additional written correspondence from FDA. However, you inaccurately interpret those previous communications with FDA. For your reference, we have attached the previous Warning Letters (2005, 2008) as well as the meeting minutes from your meeting with FDA in 2011. As you will note in reviewing these documents,

several of the items you addressed in your response letter were previously discussed and addressed by FDA:

- During the meeting on September 21, 2011, the use of the word depression was discussed. You stated that depression in itself is not a disease and in order for depression to be a disease it needs to be chronic and not acute. This is similar to the statements in your recent response dated May 26, 2017. In response, FDA personnel explained that this is inaccurate and provided the counter example of seasonal depression. It was clearly communicated to you that the use of the word depression would be difficult to separate from the disease whether chronic or occasional.

- During the meeting on September 21, 2011, the statement regarding easing symptoms associated with fever, colds, coughs, and flu was discussed. You stated that you were referring to the symptoms and not the curing of fevers, colds, and flu. This is similar to the statements in your recent response dated May 26, 2017. FDA personnel explained that the statement does constitute as a disease claim because you were referring to a symptom that has an affect or characteristic signs associated with it to a specific class of diseases. It was explained that a fever is a symptom of a cold. Further, mitigating a sign or symptom of a disease is a disease claim.

- During the meeting on September 21, 2011, the statement regarding birth defects and wounds was discussed. It was explained by FDA personnel that damage to the skin, which is an organ, can constitute a disease claim, including a puncture to the skin. This is similar to the statements in your recent response dated May 26, 2017, where you note the examples provided for wound healing included scrapes and bruises. The mention of examples such as scrapes and bruises after "wound healing" does not limit the statement to only those examples and could be construed to include more significant wounds such as punctures, as mentioned during the meeting. It was additionally explained that while specific disease names may not be mentioned, that does not mean the statements made about a product are not considered disease claims.

- During the meeting on September 21, 2011, the claims regarding killing cells were discussed. It was explained that while it may appear you are making an objective claim, FDA looks at the context which that claim was made and that other references on your website provide the context of affecting cancer.

- In the Warning Letter SEA 08-18, dated May 20, 2008, FDA listed claims on your website which caused your products to be drugs because they were intended for use in the cure, mitigation, treatment, or prevention of disease. Several of these claims remain on your website today, including, but not limited to, the scientific publications which are cited on your website.

- In the Warning Letter Ref. No. CL-04-HFS-810-131, dated February 24, 2005, FDA listed claims on your website which caused your products to be drugs because they were intended for use in the cure, mitigation, treatment, or prevention of disease. Several of these claims remain on your website today, including, but not limited to, claims related to birth defects, wound healing, extending life expectancy for terminally ill patients, reducing inflammation, and Type 2 diabetes.

Your response does not address the majority of the claims listed in Warning Letter SEA 17-14 that cause your products to be unapproved new drugs and misbranded drugs.

In regard to the Dietary Supplement cGMP violations and the failure to establish a system of production and process controls, your response is inadequate. Your response states you now maintain the Master Manufacturing Records (MMRs) for each of your dietary supplements. Your response states that your firm maintains highest levels of potency, purity and quality, insists on USP Pharmaceutical grade certified ingredients, only use cGMP certified manufacturing facilities, and that your products must meet or exceed all labeling claims. However, your response provides no documentation or procedures to indicate how your firm ensures your products meet your expectations. The Warning Letter specifically references the failure to establish written procedures for 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 the approving for release, or rejecting, any packaged and labeled dietary supplement for distribution, as required by 21 CFR 111.127(h). Your response did not address the failure to establish these procedures. The MMRs provided by your firm are an important first step in your 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 establish specifications and whether to approve and release the products for distribution. However, the MMRs alone are not adequate to address the violation listed in the Warning Letter. Additionally, the MMRs provided do not include all necessary elements as required by 21 CFR 111.210. As stated in the Warning Letter, you have certain obligations as a distributor that contracts with a manufacturer to manufacture, package, and label dietary supplements on your behalf that your firm releases for distribution.

On previous inspections, our investigators have provided you with the regulations for cGMPs of dietary supplements, 21 CFR 111. It is your responsibility for ensuring your firm is in compliance with FDA regulations. FDA guidance is available including FDA's *Guidance for Industry: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide* online at: https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatory information/dietarysupplements/ucm238182.htm.

As stated in the Warning Letter, violations of 21 CFR 111 render your products adulterated dietary supplements under section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 342(g)(1)]. By failing to follow the cGMPs in 21 CFR 111, your products are considered adulterated under FDA law. We respectfully disagree with your request for retraction or public apology regarding this determination of adulteration.

Your response requests the posting of your letters to FDA's website. FDA's procedures regarding posting Warning Letter responses to our website can be found in our Regulatory Procedures Manual Chapter 4-1-8 through links on FDA's website at www.fda.gov. A recipient of a Warning Letter must request that FDA post their response to the FDA website. Additionally, the agency has reserved the right not to post certain responses, such as when posting likely would mislead the public about the safety or efficacy of a regulated product. As your response dated May 26, 2017, makes inaccurate statements regarding FDA's past interactions with your firm and inaccurately interprets the definition of disease claims, we will not be honoring your request to post your response to FDA's website at this time.

Your response includes information about other firms' websites. While we will forward this information to the appropriate personnel, you can find additional information about submitting trade complaints to FDA at www.fda.gov and can reach Seattle District's Consumer Complaint Coordinator at 1-800-353-3965 (toll-free).

FDA has provided your firm with the opportunity to voluntarily comply with FDA laws and regulations. It is our expectation that you remedy the violations listed in the Warning Letter in an expeditious and complete manner. Please submit an additional response with your corrective actions to: Jessica L. Kocian, Compliance Officer, FDA Seattle District Office, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021.

Sincerely,

Jessica L. Kocian
Compliance Officer

Enclosures:
Warning Letter Ref. No. CL-04-HFS-810-131 dated February 24, 2005
Warning Letter SEA 08-18 dated May 20, 2008
Memorandum of Meeting held September 21, 2011