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

July 31, 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 July 12, 2017, written in further response to Warning Letter SEA 17-14, dated May 12, 2017, and FDA's subsequent letter dated June 30, 2017.

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

Your response asks for direction to where FDA posts Warning Letter responses on our website. FDA Warning Letters can be found at: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm. Warning Letter responses can be found at this website as well and there is a link specifically to browse Warning Letters with response letters. FDA's procedure for "Requests to Post Response on Internet" can be found in the Regulatory Procedures manual Chapter 4-1-8 through links on FDA's website. Posted Warning Letters can also assist you in reviewing statements that FDA has determined cause products to be considered unapproved new drugs.

Your response does not indicate you have made any corrections in response to the Warning Letter or FDA's subsequent letter dated June 30, 2017. Review of your website after receiving your letter dated July 12, 2017, found that all the claims listed in the Warning Letter remain present. FDA does not endorse any particular medical or scientific authority as you have requested we provide. FDA subject matter experts review statements made in product labeling to determine if the statements cause products to be considered unapproved new drugs. In Warning Letter SEA 17-14, previous Warning Letters and our subsequent correspondence, and the meeting held with you in 2011, FDA has provided you with an assessment of your labels and point-of-sale website, which cause your products to be considered unapproved new drugs.

With regard to dietary supplement cGMPs, FDA's regulations in 21 CFR 111 became effective August 24, 2007, and the compliance date for businesses with fewer than 20 full-time equivalent employees was June 25, 2010. As stated in our previous correspondence, on previous FDA 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. Regardless of the number of employees, you are expected to comply with the regulations, which include establishing and following written procedures as required.

With regard to the list of documents your response states you maintain for each product, we reiterate, as stated in our June 30, 2017 letter, that the example MMRs provided in your initial response to the Warning Letter, dated May 26, 2017, do not contain all elements required in 21 CFR 111.210. Furthermore, there may be additional records required for your review as an own label distributor to ensure the products you receive conform to established specifications. Your response did not include examples of the documents you receive for each product. Your response did not include whether you have established a written agreement with the contract manufacturer to delineate responsibilities and have a clear understanding of what cGMP activities your contract manufacturer is completing in regard to your products. We note that FDA does not certify contract manufacturers. Your response remains inadequate at this time and we continue to be concerned about the compliance of your dietary supplements.

It is our expectation that you remedy the violations listed in the Warning Letter in an expeditious and complete manner. Future FDA inspections will verify your compliance with FDA laws and applicable regulations. As stated in the Warning Letter, failure to promptly correct the violations may result in enforcement action without further notice.

Sincerely,

Jessica L. Kocian
Compliance Officer