August 13, 2017

Jessica L. Kocian
Food and Drug Administration
22215 26th Avenue S.E., Suite 210
Bothell, Washington 98021

RE: Your Followup Letter Dated July 31, 2017 (RE: WL SEA 17-14)

Hello Jessica, I am going to attempt to answer each of your queries in the order of your follow-up letter.

First of all, thank you for providing me with the link to your warning letters. I see that the FDA posted a very small number of response letters which were selected from only a handful of affected businesses. I am puzzled that, although the FDA has issued thousands upon thousands of warning letters, you have chosen to publish only 37 *(of what I can only assume are thousands of)* responses received. Additionally, these postings only go back five (5) years.

Out of thousands of warning letters the FDA has issued you have only published an average of 7.4 response letters per year?! VitaPurity believes this is completely unfair to the businesses affected by your warnings and totally misleading to the American public. By arbitrarily censuring the majority of response letters, the FDA makes it seem as if those of us who have responded to your warning letter(s) have actually disregarded them because of our absence on your website!

Again, VitaPurity requests that you publish ALL of our response letters and let the American people decide what is right or wrong with them.

During the past 13 years of working with the FDA VitaPurity has made a great number of changes to our website at the request of your various investigators. We even addressed four of your complaints in WL SEA 17-14 by making two label changes and providing proof that your other interpretations did not meet the standards of a violation per FDA rules.

You have repeatedly cited the 2011 FDA inspection yet ***you have conspicuously failed to mention the later FDA inspection that VitaPurity underwent in 2013 wherein we made such wide and comprehensive changes that we received three (3) FDA follow-up letters between January, 2014 and July, 2014 recognizing our actions.*** On July 31, 2014 the FDA Director of your Compliance Branch, Lisa Althar wrote us a very nice letter providing us with a copy of the EIR and advising us that, ***"No response from you is required"*** *{see attached}.*

VitaPurity Nutraceuticals
(a Division of VitaPurity Corporation)
P.O. Box 5462, Central Point, OR 97502-0060 **Website:** www.vitapurity.com **Contact:** http://www.vitapurity.com/index_co.html
Orders: (877) 878-PURE **Phone:** (541) 664-1942 **Fax:** (541) 664-1885

During the past four (4) years no substantial wording has changed on the VitaPurity website or with any VitaPurity product labels. We met FDA standards after the 2013 inspection. Why are you now calling into question statements made on our website and on our product labels that were already worked out four (4) years ago?

Quite frankly, the VitaPurity Nutraceuticals website has actually become rather confusing for the average consumer since, over the course of 13 years, the FDA requested that we change or remove dozens of very important informational items which VitaPurity, in the spirit of cooperation, fully complied with.

With regard to the documents that we require and maintain from our contract manufacturer, they were reviewed by your investigator and found to be in order with the exception of the latest obligation to now maintain Master Manufacturing Records. That is why I did not include the other documentation in my previous letters to you; they were not an issue.

FYI, our contract manufacturer was puzzled that the FDA now required MMRs from us since we are not a bona fide manufacturer, only actual contract manufacturers had been required to keep them. ***Our contract manufacturer advised us that we were the only non-manufacturer they were aware of that the FDA demanded keep those records as well.***

Finally, I am surprised at your expression of *"concern"* about the FDA compliance of VitaPurity's nutritional supplements ***when the issue has nothing to do with the safety, purity or potency of VitaPurity products.*** The issue simply appears to be how we promote our products. Additionally, since we conducted a major rewrite of our website and product labels after the 2013 FDA inspection, I cannot see where VitaPurity is *"all-of-a-sudden"* out of compliance with the FDA in such a big way.

I believe our website wording and product labeling fall well within FDA rules and regulations as established by the United States and the international medical and scientific communities' definitions.

We have made every effort to cooperate with the FDA during the past 13 years and we have been fully compliant for at least the last four (4) years. ***You should not have to be reminded that FDA regulations allow nutritional supplement companies to make structure/function claims. VitaPurity will always keep those regulations in mind if/when we change or add any wording to our website and/or product labels.***

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ATTACHMENTS:

1.) VitaPurity Corporation's December 30, 2013 response to the December 11, 2013 FDA inspection conducted by **FDA Consumer Safety Officer Barbara J. Rincon**, and;

2.) FDA letter dated January 30, 2014 from **Kate Bent, RN, PhD, Acting FDA District Director**, confirming receipt of our December 30, 2013 letter **(NO RESPONSE FROM VITAPURITY WAS REQUIRED)**, and;

3.) VitaPurity Corporation's February 27, 2014 detailed response to the December 11, 2013 FDA inspection, and;

4.) FDA letter dated March 10, 2014 from **Ann M. Adams, PhD, Acting FDA District Director**, confirming receipt of our February 27, 2014 detailed response **(NO RESPONSE FROM VITAPURITY WAS REQUIRED)**, and;

5.) FDA letter dated July 31, 2014 wherein **Lisa M. Althar, FDA Director of Compliance Branch**, courteously provided VitaPurity with a copy of the Establishment Inspection Report (EIR) from the December 11, 2013 inspection. **(NO RESPONSE FROM VITAPURITY WAS REQUIRED)**.

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REQUESTED DOCUMENTATION:

1.) A copy of the Establishment Inspection Report (EIR) from the November 01, 2016 FDA inspection.

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To Your Health,

Otto Roder
President
VitaPurity Nutraceuticals
(a division of VitaPurity Corporation)
P.O. Box 5462
Central Point, Oregon 97502-0060
Phone: (541) 664-1942
Fax: (541) 664-1885