



# VitaPurity

Welcome to Recovery, Good Health and a Long Life!

[www.vitapurity.com](http://www.vitapurity.com)

July 12, 2017

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

**RE:** Your Followup Letter Dated June 30, 2017 (RE: WL SEA 17-14)

Hello Jessica, I am thoroughly perplexed by your followup letter to our response to the FDA Warning Letter SEA 17-14. We have cooperated fully with all United States Food & Drug Administration personnel during the past 13 years of contacts with your organization. **Over those many years we even removed information from our website and our product labels that the odd investigator found to be questionable even when they were wrong according to your own FDA guidelines.** VitaPurity Corporation did this to show the FDA that we were always willing to be cooperative and pleasant with your organization.

Over the years we have provided medical and scientific evidence regarding disease and non-disease states from such esteemed organizations as:

- 1.) **The Journal of the American Medical Association;**
- 2.) **The United Nations World Health Organization;**
- 3.) **The Center for Disease Control in Atlanta;**
- 4.) **The Mayo Clinic, etc.**

The above listed organizations are not friends of nutritional health companies, they are 100% on the side of pharmacological medicine. **It is precisely because of their stand that we have chosen to use those organizations as medical sources when we seek guidance on disease states.** Your letter seems to indicate that you do not respect these organizations as capable of determining disease and non-disease states. **Is this the case?**

In order for us to determine whether or not a structure/function claim is allowed or not allowed by FDA regulations we need to all be *"on the same sheet of music"*. Jessica, if you do not respect the above listed organizations as definitive sources of medical and scientific authority then you are in direct violation of your own FDA regulation **21 CFR 101.93(g) section D, Criterion 2** which explicitly states:

***"You can look to medical texts and other objective sources of information about disease to determine if a label statement implies treatment or prevention of a disease"***

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**VitaPurity Nutraceuticals**  
(a Division of VitaPurity Corporation)

P.O. Box 5462, Central Point, OR 97502-0060 Website: [www.vitapurity.com](http://www.vitapurity.com) Contact: [http://www.vitapurity.com/index\\_co.html](http://www.vitapurity.com/index_co.html)  
Orders: (877) 878-PURE Phone: (541) 664-1942 Fax: (541) 664-1885

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If you have some personal favorite medical and/or scientific sources that you respect then please provide us with a list of those organizations so that VitaPurity can also consider their opinions when we are researching whether or not we can make a structure/function claim per FDA regulations. Following are a few conditions that we should have no argument about:

Let's stop rehashing things like ***"Occasional Depression"*** which is a normal human response to difficult situations. Again, the United Nations World Health Organization states, ***"Depression as a disease should be clearly differentiated from depressive symptoms or moods, which are an integral part of human emotions."***

There should also be no need to debate whether or not a sunburn is a disease. Billions of people experience sunburn time and time again throughout the summer months around the world with no ill effects. ***If someone's skin is not seriously compromised or diseased they do not have to worry about occasional sunburn.***

In fact, the Mayo Clinic had this to say about the management of sunburns, quote:

*"Sunburn — red, painful skin that feels hot to the touch — usually appears within a few hours after too much exposure to ultraviolet (UV) light from sunshine or artificial sources, such as sunlamps. Sunburn may take several days or longer to fade...If you are sunburned, home remedies and treatments can help soothe your skin as it heals."*

If the Mayo Clinic recommends that we treat our sunburns with ***"home remedies"***, then they are clearly not very worried about us going outside into the sunshine.

**Sunburn is not a disease based on your own FDA guidelines.** It is evidence of having gotten a bit too much sun. One can take care of the discomfort by applying Aloe Vera, Vitamin E, or Vitamin C, they might even choose to take some VitaPurity Ellagic Ultra or VitaPurity Citral from Lemon Grass to help speed up the process.

Our skin is a barrier that protects us against all kinds of external threats to our health. ***That is what skin was designed to do!*** From solar radiation, to germs, to bacteria, to industrial and environmental toxins, to certain parasites, and to a bundle of other external threats, ***healthy skin is working 24-hours a day to protect our bodies against everything that planet Earth and the cosmos can throw at us.***

As with our immune system, our skin protects us from disease. Does it get injured in carrying out that task? ***All the time! Our bodies are in a constant state of bombardment from external threats 24-hours a day, 365 days per year! That's life on planet Earth!***

Our skin may be considered to be an *"organ"*, but our skin is much more than that. If one holds to your argument then it would dictate that all 7 billion people on this Earth are living in a perpetual and continuous diseased state because our skin is constantly being bombarded and compromised...***your assessment is simply not true. Never forget that our bodies have a wonderful, God-given ability to heal ourselves. Your skin experiences damage constantly in its protective role, this is its normal function, but it is also continually healing itself.***

As a result, *"scrapes, bumps and bruises"* or even puncture wounds (*sometimes received at the hands of doctors drawing blood with those very large needles, in recreational piercing parlors, or in tattoo shops*) do not rise to the point of causing us to be in a diseased state...***remember that our bodies heal themselves.***

**Unless the FDA is going to shutdown the piercing and tattoo shops that clearly and intentionally damage skin, then there is an obvious non-disease state even when deliberately choosing to damage that protective organ.** The skin is great at quickly sealing itself off when compromised. Therefore, FDA regulation **21 CFR 101.93(g) section D** allows us to make structure/function claims involving “scrapes, bumps and bruises” to our skin.

Jessica, since you have chosen to dismiss our medical and scientific sources as irrelevant I am hesitant to go into a lot of debate about disease states in this letter, however, there is something I would like to mention...

Have you ever heard of the saying, “*feed a cold and starve a fever*”? **That saying has been around since about the year 1574 AD because people have always known that you treat a cold differently than you do the symptom of a fever.** I know that we can debate the efficacy of that old saying, but the bottom line is that a cold is not a fever, and a fever is not a cold. **Colds are caused by viruses and, for the most part, fevers are the result of bacterial infections**, yet, in your letter you state, quote, “*FDA personnel explained that...a fever is a symptom of a cold.*” **I respectfully disagree with your assumption.** A stuffy nose and excess mucous production coupled with an occasional sore throat can make up the symptoms of a cold. **A fever, however, is RARELY, if ever, a symptom of a cold.**

If you are always going to argue “*worst case scenarios*” in order to defeat every instance wherein VitaPurity makes a structure/function claim then we believe that you are going directly against your own FDA regulation **21 CFR 101.93(g) section D** which clearly allows us to make claims when a condition is, quote, “**...associated with a wide range of disease and non-disease states and do not necessarily imply an effect on a specific disease.**”

Again, the U.S. Food & Drug Administration’s “*Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide*” Section D, Criterion 2, Subpart titled, “**How can I determine if a claim is about a sign or symptom that is “characteristic” of a disease?**”, states *{emphasis mine}*:

**“You can look to medical texts and other objective sources of information about disease to determine if a label statement implies treatment or prevention of a disease”**

That is exactly what VitaPurity does. The guideline continues:

“...signs or symptoms *{can be}* associated with a wide range of disease and non-disease states and do not necessarily imply an effect on a specific disease. **For example, although ‘improves absentmindedness’ might imply treatment of Alzheimer’s disease and ‘relieves stress and frustration’ might imply treatment of anxiety disorders, both of these signs are also characteristic of non-disease states. So, if there is no context linking them to a disease, they would be appropriate structure/function claims.**”

I am sure you know that if we believed every worst case nightmare scenario that came down the pike we would have to stop eating most foods and we could forget about drinking fruit juices, soft drinks and much more because, in those very worst of scenarios, just about everything we put in our mouths can cause cancer, heart disease and a plethora of other horrible illnesses. **I’ll take my chances with my food & drink options and forego starving to death as the “healthy alternative”.**

Jessica, here is your own FDA definition of a disease, it can be found at the U.S. Food & Drug Administration “*Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide*” Section D which asks:

“**What is the definition of a disease?**” Section 101.93(g) answers this by defining disease as:

*“...damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension)...”*

It is clear that the FDA’s definition of disease is one where damage or infection or injury would lead to the dysfunction of an organ, part, structure or system of the body. VitaPurity’s structure/function claims never involve curing, treating or preventing disease. We only speak to the maintenance of good health. Our motto is, **“Welcome to Recovery, Good health and a Long Life.”**

***We believe that the American people are intelligent human beings and understand that our claims are not in violation of FDA regulations. We also believe that you do not hold to that same opinion of the American people given your arguments. VitaPurity is concerned that too many FDA employees have taken the position that the American people are somehow ignorant and need to be protected from their own ineptitude.***

You have elected not to post our responses to your warning letters and other communications because our responses do not agree with some of your interpretations. ***VitaPurity believes we have the right to refute what we believe are misunderstandings by the FDA, and that you should not penalize us for our views by keeping our letters from the American people. Please direct me to a link where you have posted responses from other companies that met your standards as being “appropriate” to publish.***

Finally, since I am the only employee that deals with returns, complaints, recalls, etc., I do not need to write myself an SOP on what I would do in those situations. I would need written SOPs if I hired employees to do those tasks.

***Additionally, you are mistaken if you think that the only written documentation we keep to determine the purity, potency and specifications of our products is MMRs.*** Did you actually read our response to Miriam’s FDA warning letter? ***To recap; this last inspection was the first time in 13 years of FDA inspections that any FDA field employee ever asked us for an “MMR”, we have now added them to the list of written documentation we keep on file for each and every nutritional supplement in our product line.***

The documentation we keep includes, but is not limited to:

- 1.) Certificates of Analysis;
- 2.) Near Infrared Spectroscopy testing;
- 3.) Master Manufacturing Records;
- 4.) Periodic independent lab testing results;
- 5.) Microbiology testing;
- 6.) Current cGmp certification on the contract manufacturer used;
- 7.) FDA certification of contract manufacturers used (*when available*).

I look forward to receiving a list of medical and scientific authorities that you turn to in order to determine whether a condition is a disease or not, and please provide an FDA website link to the letters from companies whose responses have met with your approval.

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