



# VitaPurity

Welcome to Recovery, Good Health and a Long Life!

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

May 26, 2017

Miriam R. Burbach  
Food and Drug Administration  
Attn: Jessica L. Kocian, Compliance Officer  
22215 26<sup>th</sup> Avenue S.E., Suite 210  
Bothell, Washington 98021

**RE: WL SEA 17-14, Dated May 12, 2017**

Hello Miriam, thank you for giving me the opportunity to respond to the concerns you noted in your letter dated May 12, 2017. The complicatedness we have experienced over the past 13 years in our dealings with the Food and Drug Administration stems from the ongoing confusion caused by attempting to run VitaPurity Nutraceuticals on the opinions of one FDA agent after another **(with each new FDA agent not agreeing with the last one!)**.

Fortunately, in 2012 Lisa Elrand provided us with the specific FDA regulation that addresses most, if not all of the issues that you have brought up in your warning letter. The FDA regulation that allows us to make the structure/function claims that we do is **21 CFR 101.93(g) section D** titled: *“How Do I Determine if a Claim is a Structure/Function Claim or a Disease Claim?”*, and the ten (10) criterion that go along with that section.

**I am absolutely dismayed that you would write in your warning letter that, quote, “We found serious violations of the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements...”, when the only two “faults” observed by your investigator were that we had not requested and kept on file “Master Manufacturing Records” for each of our dietary supplements.** Of course, no other FDA investigator ever mentioned this obligation to us before. VitaPurity has voluntarily corrected this alleged impropriety and we now maintain those records.

***Miriam, with all due respect, I must disagree with your assertion that VitaPurity has committed “serious violations” in the production, oversight and manufacture of our dietary supplements. Additionally, we do not make claims which would indicate that our products are intended for use as drugs.***

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**VitaPurity Nutraceuticals**

*(a Division of VitaPurity Corporation)*

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Following is a list of items that VitaPurity has voluntarily removed, modified or maintained with explanations as needed:

### **CITRAL FROM LEMON GRASS:**

1.) **ORIGINAL WORDING:** *“Used for hundreds of years to help lift depression...”*

2.) **UPDATED WORDING:** *“Used for hundreds of years to help with occasional depression and bad moods.”*

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1.) **ORIGINAL WORDING:** *“Helps reduce fever by lowering body temperature.”*

2.) **UPDATED WORDING:** *“Helps ease symptoms of fevers, coughs, sneezing and runny nose.”*

Although common colds and the flu are established diseases, **fevers, coughs, sneezing, and runny noses are not diseases nor are they necessarily symptomatic of a specific disease.** In fact, a fever is simply a common medical sign characterized by an elevation of body temperature above the normal range of 36.5-37.5°C (98-100°F) due to an increase in the body's temperature regulatory set-point.

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?”**, allows for the use of the terms “fever” and “coughs” since these are symptoms, quote, **“...associated with a wide range of disease and non-disease states and do not necessarily imply an effect on a specific disease.”**

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I am a bit perplexed that we are still going over the same topics that VitaPurity proved our compliance with, beyond a reasonable doubt, to FDA Directors, Officers and Investigators way back in 2012.

Most of your assertions in your FDA warning letter fail to be supported by such world renowned medical organizations as the **United Nations World Health Organization** or the **Journal of the American Medical Association**, etc. Your interpretations also fail to abide by FDA regulation **21 CFR 101.93(g) section D:** *“How Do I Determine if a Claim is a Structure/Function Claim or a Disease Claim?”*. For example:

In your warning letter under, **Citral from Lemon Grass**, you attack us for making the label claim that our product, quote, *“Combats occasional depression”*. **Your statement is considered incorrect according to all of the major United States and United Nations medical organizations, along with the U.S. Food and Drug Administration.**

Depression is a normal emotional response to stress and it is experienced by the overwhelming majority of the more than seven (7) billion people on this planet from time to time. **Individuals that are unable to experience appropriate depression are the ones that can be classified as “abnormal” and living in a diseased state.** Normal responses ARE NOT disease states.

Following is a direct quote from an informational pamphlet distributed by the **Community Health Center** (*Community Health Center is a United Way company*) {emphasis mine}:

**“Depression is a very common symptom that can affect anyone. It is most often a normal response to difficult situations.”**

The following is an excerpt taken from the Introduction to the **United Nation’s World Health Organization** booklet titled, **“Conquering Depression”** {emphasis mine}:

**“The emotions of feeling sad, unhappy or disappointed are part of a human being’s normal existence, and are experienced by everyone almost on a daily basis.** Such emotions may be associated with failure in academics, setback in a relationship, loss in a financial investment, break-up of a love affair, or with the death of a loved one...after feeling low for a few days during which time there can be changes in the sleep pattern and appetite, disinterest in daily chores etc., the person...usually returns to normal.

**Depression as a disease should be clearly differentiated from depressive symptoms or depressive moods, which are an integral part of human emotions.** There are qualitative as well as quantitative differences between a state of unhappiness in reaction to the adverse events in the world outside, and depression as a disease state. **It is essential for doctors, the general public and health planners to clearly understand that.”**

Miriam, the United Nations World Health Organization clearly disagrees with your statement and, in fact, concludes the exact opposite of what you and some other FDA investigators tenaciously maintain. Again, the United Nations W.H.O. unmistakably states that, **“Depression as a disease should be clearly differentiated from depressive symptoms or depressive moods, which are an integral part of human emotions.”**

2 of 9

Finally (*with regard to depression*), 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”**

I have provided you with two highly respected objective sources of information above. 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.**”

According to your own FDA guidelines, our statement, **“Combats occasional depression”** is allowable since our statement is, by those guidelines, **“also characteristic of non-disease states”**.

**EXAMPLE:** I get depressed whenever I receive a warning letter from the FDA threatening *“enforcement action”*. According to your understanding I have a disease since I am depressed on a regular basis (*whenever I receive an FDA warning letter!*). Do you really think that I have clinical depression and need to see a doctor? **Of course not!**

The occasional depression I experience is a normal response after receiving an intimidating letter from a massive government agency that continues to make repeated, and often unjustified, threats of enforcement action. A government agency with the power to wipe out careers, wipe out incomes, wipe out businesses, and destroy the lives of our customers, many who rely on VitaPurity products to help maintain their *“Recovery, Good Health and a Long Life.”*

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## **ELLAGIC ULTRA:**

In your warning letter under, **Ellagic Ultra**, you claim that, quote, *“Your website includes disease claims in the form of citations to publications or references.”* One of the statements you highlight is, quote, *“...the American Cancer Society wrote that Ellagic Acid may, ‘reduce...birth defects...and promote wound healing’...”*

What is conspicuously absent from your statement is the omission of our qualifying addendum immediately following the words, *“wound healing”*. The VitaPurity statement actually reads, quote, **“Additionally, the American Cancer Society wrote that Ellagic Acid may, ‘reduce...birth defects...and promote wound healing’ (i.e. scrapes bumps and bruises).”**

**Miriam, I am deeply concerned that you would misquote us by this grievous omission.**

Neither our above statement nor the similar *“scrapes, bumps and bruises”* statement we make for our **VitaPurity Buffered Vitamin C Crystals** violates FDA guidelines. As I am sure you already know:

- 1.) *A birth defect is not considered a disease, and;*
- 2.) ***With regard to a wound, it is still classified as an injury no matter how serious the damage is. Furthermore, the manner by which both the American Cancer Society and VitaPurity Nutraceuticals uses the term “wound healing” clearly refers to simple scrapes, bumps and bruises, not to anything that would constitute a disease.***

The U.S. Food & Drug Administration *“Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide”* Section D states:

**“What is the definition of a disease?”** Section 101.93(g) defines 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 the infection/injury would lead to a normal bodily operation not functioning properly. The American Cancer Society and VitaPurity's use of the word "wound" does not suggest an injury that would cause any dysfunction or inability to use the injured member, for example, with a shotgun blast to the chest or having a leg torn off in a car accident, etc.

***We believe that American citizens are intelligent human beings and we believe that anyone in their right mind understands that we are referring to normal, everyday scrapes, bumps and bruises that are taken care of at home without the need of a visit to the emergency room.***

The injuries we refer to are the types that natural preparations such as Aloe Vera, vitamin E, vitamin C, Ellagitannin Complex (*i.e., ellagic acid*) and many others are quite helpful with. These injuries do not rise to a place that constitutes disease by FDA statute. The worst thing an everyday scrape, bump or bruise can do is cause temporary discomfort and/or leave a bit of a scab that direct application of vitamin E or the eating of raspberries (*providing ellagitannin complex*) have been smoothing out for hundreds, if not thousands of years.

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## **BUFFERED VITAMIN C CRYSTALS:**

1.) **UNCHANGED:** *"VitaPurity Also Offers Help Against The Flu"*

This statement remains unchanged because it does not violate FDA guidelines. According to The U.S. Food & Drug Administration "Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide" Section D, Criterion 4, Sub-Section 3, titled, "**Can I use citations of publications that relate to my product's intended use in labeling if the publication title or the journal name mentions a disease name?**" It states:

***"Yes, but some limitations apply...If the citation is used in labeling, its context determines if it is a disease claim. A citation that is...included in a balanced discussion of the scientific literature, not excessively prominent relative to other citations, and provides legitimate support for a structure/function claim made for the product would not be a disease claim."***

The reference(s) noted above are specifically about preparation and common sense in helping dads and moms put together a home "Flu Kit". Additionally, the reader must open another page to actually read Stephanie Pierson's information. In Ms. Pierson's article VitaPurity is but a tiny line nearing the end of the report alongside many other pharmacological and natural recommendations by Ms. Pierson to be included in her "Flu Kit".

Vitamin C has been recommended by conscientious dads, moms and doctors for hundreds of years to promote good health and to help ease the symptoms of colds and/or flu. It is clearly a wise recommendation, and there are volumes of documentation to support this. Additionally, the information provides legitimate support for structure/function claims. Per the above FDA guideline this is not a disease claim.

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## CORAL CALCIUM WITH D3:

\*\*\* Discontinued \*\*\*

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Several years ago VitaPurity removed all problematic words from our website including, but not limited to, “*cancer, cancerous, malignant, malignancy, tumor(s), heart disease, heart attack(s)*”, etc. and replaced them with very confusing substitutions such as, “*bad cells, malevolent cells, dangerous cells, life-threatening cells, invading cells, harmful cells, heart trouble, etcetera*”.

Upon completion of this task, ***FDA Compliance Officer Lisa Althar stated that by removing the above listed “trigger” words the FDA would no longer consider the statements associated with those words as troublesome.***

In a teleconference call conducted on September 21, 2011, ***FDA Senior Regulatory Review Officer, Quyen Tien admitted that VitaPurity had so effectively cleaned up our website that the average consumer could no longer make the connection between our products and cancer.*** Mr. Tien said, quote, “*To the example of Citral {and} lemon grass killing life-threatening cells. To the untrained eye it doesn't look like it's a very volatile claim or an objective claim that FDA would point out.*”

***If the general public is not able to specifically identify our products as cancer/disease cures, treatments or preventives then we have obviously not violated FDA regulations involving disease or structure/function claims.***

With regard to any VitaPurity website statements or label claims wherein we speak about our products' ability to help “*ease symptoms or make someone feel better*”, these are totally benign in their context. ***Simply easing a symptom or making someone feel better does not prevent, treat or cure any disease in any way.***

Do you think that waking up to a hot cup of coffee, a couple of greasy donuts and a cigarette will prevent, treat or cure disease? After all, ***tens of millions of Americans wake up to that precise, unhealthy start to their day, and I hear it makes them feel pretty darned good!*** However, we both know that if they stick to that type of a diet on a regular basis it will almost certainly compromise their health.

Again, my point is that helping to ease symptoms does not indicate any correlation with preventing, treating or curing disease.

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VitaPurity Nutraceuticals does not encourage people to stop undergoing any treatment prescribed by their doctors, up to and including chemotherapy and radiation (***which we both know is extremely destructive and often deadly to the patient***). What VitaPurity does emphasize to our customers is that they pay close attention to whatever they choose to put into their bodies especially when undergoing harsh, toxic, and often life-threatening medical and/or drug treatments.

***With the valuable (and some might say, priceless) information VitaPurity provides along with the essential nutritional assistance we offer, we hope to help people hold on to as much health and life as they can if they choose to undergo immune system destroying medical treatments such as chemotherapy and radiation.***

By providing people with both the information they need to make informed decisions and the nutritional supplements they need to stay healthy we actually end up invisibly assisting and working alongside doctors and others in the medical community by helping physicians to be more successful when they prescribe life-threatening treatments such as chemotherapy and radiation.

***When VitaPurity is able to help someone maintain a robust immune system we are actually helping them to better their chances that their “doctor prescribed” pharmaceutical treatment regimen will have a higher likelihood of success.***

Miriam, there will always be gray areas, and areas where lines of interpretation blur, ***these are not in any way violations of FDA guidelines.*** They fall into that area where science and medicine are in a constantly changing matrix, and the understanding of medical conditions, disease states and normal bodily functions is in perpetual flux.

As always, upon notification that a condition has been deemed a disease or a non-disease, and which affects a VitaPurity product, VitaPurity Nutraceuticals promises to act appropriately to those changes while continuing to maintain compliance with FDA guidelines.

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## **FINAL NOTES:**

The U.S. Food & Drug Administration “*Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide*” Section D states: ***“It may not be possible always to draw a bright line between structure/function and disease claims.”*** VitaPurity fully agrees.

After years of cooperating with the FDA and its many compliance officer’s interpretations of FDA guidelines (*right or wrong*), I believe our website is void of any flagrant violations.

VitaPurity would appreciate that the FDA publicly declare that we have strictly adhered to “*truth in advertising*”, that we have used the highest-quality ingredients in the manufacture of our products, and that VitaPurity administration and staff have always shown FDA officials courteous professionalism when working with them.

***Disappointingly, the FDA has been quick to release over the internet the various negative letters sent to VitaPurity, however, never once were our responses posted.***

***If the FDA chooses not to issue a complimentary letter about VitaPurity Nutraceuticals then we respectfully request that you at least post our responses to each of your letters to us. FDA regulations state that you are supposed to do that, yet not one of our responses can be found on your website.***

Even though VitaPurity believes it broke no FDA rules in the past when we provided scientific references, unsolicited customer testimonials, and valuable medical information to our customers, we still voluntarily removed these items at the request of FDA compliance officers over the years.

***VitaPurity would now like to see the FDA use a fair and even hand when enforcing their guidelines.*** As I said to a journalist in a Washington Post interview a few years back, it is indeed time for the FDA to ***“go after the bad guys”*** who are selling products that don't work, products that are devoid of active ingredients, companies that give false information on their websites and in their literature ***and companies that continue to promote their products in a manner that VitaPurity is forbidden to do so by the FDA.***

VitaPurity has repeatedly advised the FDA about several illegal businesses for the past thirteen (13) years. Yet no apparent action has been taken by the FDA in these cases. I have been astounded at the evident lack of concern shown by the FDA toward the illegal practices of these rogue companies and their brazen disregard for FDA guidelines. Instead you have chosen to fixate yourself on threatening VitaPurity Nutraceuticals with enforcement action for such innocuous statements as, *“maintains a healthy immune system.”*

For the fourteenth (14<sup>th</sup>) year in a row, I am again providing you with information on rogue nutritional supplement companies that illegally claim their supplements prevent, treat and cure a variety of diseases many of which also provide false information about their products in their website literature as well *{see multiple attachments}*.

***VitaPurity is concerned that people suffering from life-threatening illnesses are being deceived by these and many other rogue companies into buying their ineffective and possibly unsafe products while legitimate companies such as VitaPurity Nutraceuticals are silenced by the FDA and not allowed to tell the truth about the effectiveness of our products against those same diseases.***

Millions of Americans are suffering from life-threatening illnesses and they are looking for safe, effective and natural alternatives to the harsh and often deadly FDA approved medical treatments for diseases such as cancer. Our fellow Americans are being robbed by the FDA when it does not allow truthful medical information to be posted by legitimate nutritional and alternative medicine companies such as VitaPurity Nutraceuticals.

***VitaPurity continues to make compliance with the FDA our top priority while at the same time continuing to provide essential information to our customers.*** Unfortunately, since most FDA regulations are either contradicted by other sets of FDA regulations or they are subject to vague and disparate interpretation, it has been a somewhat challenging endeavor to both honor your guidelines and still provide vital information to our customers.

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***“VitaPurity maintains the very highest levels of potency, purity and quality possible within our entire product line. We insist upon USP Pharmaceutical grade certified ingredients and we only use cGMP certified manufacturing facilities ... Our products MUST meet and/or exceed all labeling claims...”***



Miriam, I am confident that VitaPurity's relationship with the FDA will remain a good one as we both strive to protect, inform and provide the American people with the very best and safest nutritional supplements available anywhere in the world.

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### **IMPORTANT UPDATE:**

I reviewed [www.fda.gov](http://www.fda.gov) and just now discovered that you have erroneously listed VitaPurity under the heading, "Health Fraud", and you have made the false claim that VitaPurity was issued a warning letter for "Adulterated Dietary Supplements".

To call our products "adulterated" without explaining that this simply means that we did not have a piece of paperwork for your investigator makes your statement an absolutely fraudulent and libelous lie. This type of accusation is completely misleading to the American people. **Adulterated means contaminated, toxic, dirty, unclean, etcetera. It has nothing to do with failing to provide a piece of paperwork (an MMR) to your investigator, which was never required of us before this last inspection. I demand a retraction or a distinct clarification of that unfounded allegation from your website along with a public apology for your false accusation.**

It is interesting how you attack us over making harmless and honest statements yet you twist the meanings of words at your convenience in order to libel VitaPurity Nutraceuticals. **SHAME ON YOU! The adulteration that you speak of has nothing to do with the quality or purity of our nutritional supplements.**

VitaPurity Nutraceuticals has always cooperated with the FDA and we have never given anyone at your agency any grief whatsoever. It hurts my heart that pharmaceutical companies such as **Wockhardt Pharmaceuticals are allowed to sell their drugs in this country after their employees physically restrained your investigator, burned documents in front of your investigator, poured items down the sink so that your investigator could not inspect them, and maintained filthy, and overflowing toilets where human waste was within a few feet of what was supposed to be sterile workstations. But, because Wockhardt could pay the FDA a 50 million dollar fine they are allowed to act like this during FDA inspections and still can go on selling their products uninterrupted within the United States. SHAME ON THE U.S. FOOD AND DRUG ADMINISTRATION FOR COMPROMISING THE HEALTH OF THE AMERICAN PEOPLE!**

VitaPurity runs a clean and healthy business that offers people alternatives to such filthy pharmaceutical companies like Wockhardt that can pay their way out of trouble, **yet you falsely accuse VitaPurity of being a business that manufactures "adulterated" products without ever explaining to the American people that the word adulterated does not really mean adulterated in the halls of the FDA!**

I think I will end this letter here. I always believed that the FDA was looking out for the welfare of the public. **I was wrong in that belief.** Maybe the other nutrition and vitamin companies are right when they claim that the FDA is actually, "the enemy of good nutritional supplement companies".

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**ATTACHMENTS:**

- 1.) Master Manufacturing Records that were available to-date. VitaPurity will request and catalogue Master Manufacturing Records for all future product runs.
- 2.) Copies of rogue nutritional supplement companies' websites that ***VitaPurity has been providing to the FDA and which the FDA has chosen to ignore for fourteen (14) years!!!***

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To Your Health,

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