



# VitaPurity

Welcome to Recovery, Good Health and a Long Life!

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

February 27, 2014

Lisa M. Elrand  
Food and Drug Administration  
22215 26<sup>th</sup> Avenue S.E.  
Bothell, Washington 98021

**RE:** Website Adjustments Made After On-Site Inspection Conducted on December 11, 2013

Hello Lisa, following is a list of items that VitaPurity has voluntarily removed and/or modified per your most recent disputation conveyed to us by FDA Consumer Safety Officer Barbara J. Rincon during the FDA inspection on December 11, 2013:

## **L-TRYPTOPHAN:**

1.) **ORIGINAL WORDING:** *“Treatment of PMDD is directed at preventing or minimizing symptoms and may include...Herbal remedies. Clinical trials suggest that L-tryptophan...may reduce irritability, mood swings, anger and headaches associated with PMDD...”*

2.) **UPDATED WORDING:** *“Treatment of {an intense form of PMS} is directed at preventing or minimizing symptoms and may include...Herbal remedies. Clinical trials suggest that L-tryptophan...may reduce irritability, mood swings, anger and headaches associated with {it}...”*

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1.) **ORIGINAL WORDING:** *“Not One Person Died from taking Nutritional Supplements!”*

2.) **UPDATED WORDING:** *“Not one person died from taking nutritional supplements as part of a healthy diet!”*

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The following disclaimer was added to the VitaPurity L-Tryptophan webpage:

**“If feelings of anger or anxiety or OCD symptoms or PMS/PDD are severe please consult your doctor or other medical professional for additional help.”**

1 of 6

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**VitaPurity Nutraceuticals**

*(a Division of VitaPurity Corporation)*

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## **LYCOPENE 25:**

1.) **ORIGINAL WORDING:** *“Previous research indicated that lycopene may ward off a whole host of ills...”*

2.) **UPDATED WORDING:** *“Previous research has indicated that lycopene is critical in maintaining the healthy functioning of organs...”*

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## **PACIFIC OCEAN SHARK CARTILAGE:**

1.) **ORIGINAL WORDING:** *“Shark cartilage has been successfully used in both animals and humans to reduce pain in bones and joints and to improve mobility.”*

2.) **UPDATED WORDING:** *“Shark cartilage has been successfully used in humans to reduce pain in bones and joints and to improve mobility.”*

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## **ELLAGIC ULTRA:**

1.) **ORIGINAL WORDING:** *“reduce...birth defects, and liver fibrosis and promote wound healing.”*

2.) **UPDATED WORDING:** *“reduce...birth defects, {maintain a healthy liver} and promote wound healing” (i.e. scrapes bumps and bruises).*

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1.) **ORIGINAL WORDING:** *“Green tea has also been shown to inhibit abnormal blood clot formation as effectively as aspirin, and to elevate...”*

2.) **UPDATED WORDING:** *“Green tea has also been shown to inhibit abnormal blood clot formation and to elevate...”*

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## **CITRAL:**

1.) **ORIGINAL WORDING:** *“...Citral is also a gentle treatment to relieve colic in infants.”*

2.) **UPDATED WORDING:** *“...Citral is also a gentle treatment to relieve occasional tummy pain that can cause crying and irritability in infants.”*

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1.) **ORIGINAL WORDING:** “*Not One Person Died from taking Nutritional Supplements!*”

2.) **UPDATED WORDING:** “*Not one person died from taking nutritional supplements as part of a healthy diet!*”

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### **MIRACLE MUSHROOM BLEND:**

1.) **ORIGINAL WORDING:** “*The New England Journal of Medicine reported that giving Shiitake to patients with probable pre-AIDS improved the patients’ general sense of well-being and improved their immune status. The report concluded that this agent may prove to be effective in the suppression of AIDS symptoms.*”

2.) **UPDATED WORDING:** “*The New England Journal of Medicine reported that giving Shiitake to patients with severely compromised immune systems improved the patient's sense of well-being and improved their immune status. The report concluded that Shiitake may prove to be effective in supporting the health of CD4 cells (aka T-Cells).*”

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The following statement was removed from the VitaPurity Miracle Mushroom Blend webpage:

**“These researchers suggested that Maitake can reduce insulin resistance, thereby increasing insulin sensitivity.”**

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### **BUFFERED VITAMIN C CRYSTALS:**

1.) **ORIGINAL WORDING:** “*...Stephanie Pierson (a Statistical Analyst in the medical field), recommended VitaPurity Buffered Vitamin C Crystals as an important supplement to support other antiviral medications...*”

2.) **UPDATED WORDING:** “*Stephanie Pierson (a Statistical Analyst in the medical field), recommended VitaPurity Buffered Vitamin C Crystals as an important supplement to include with other antiviral medications*”

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1.) **ORIGINAL WORDING:** “*Vitamin C is essential in healing wounds and recovery...*”

2.) **UPDATED WORDING:** “*Vitamin C is essential in healing scrapes, bumps & bruises and for overall recovery.*”

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1.) **ORIGINAL WORDING:** *“Another study, done by Dr. Abram Hoffer, showed an increase in the lifespan of terminally ill patients...”*

2.) **UPDATED WORDING:** *“Another study, done by Dr. Abram Hoffer, showed an increase in the lives of extremely ill people...”*

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## **JOINT RECOVERY FORMULA:**

1.) **ORIGINAL WORDING:** *“According to a review article published in the New England Journal of Medicine, **“Anti-inflammatory drugs (which include Advil®, Motrin®, Aleve®, Ordus®, Aspirin, and more than 20 others) cause over 16,500 deaths and over 103,000 hospitalizations per year in the US.”**”*

2.) **UPDATED WORDING:** *“According to a review article published in the New England Journal of Medicine, **“Anti-inflammatory drugs ... cause over 16,500 deaths and over 103,000 hospitalizations per year in the US.”**”*

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1.) **ORIGINAL WORDING:** *“The toxicity and side effects attributed to the newer COX-2 medications such as Vioxx® or Celebrex® can be extensive.”*

2.) **UPDATED WORDING:** *“The toxicity and side effects attributed to the newer COX-2 medications can be extensive.”*

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The following statement was removed from the VitaPurity Joint Recovery Formula webpage:

**“It is also showing great promise for its ability to slow or even halt the effects of arthritis.”**

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As always, when we learn of conditions that may be deemed diseases or non-diseases and which subsequently affect a VitaPurity product, **VitaPurity Nutraceuticals promises to act appropriately to research, review and apply any updates that are necessary in order to remain in compliance with the FDA guidelines as we understand them.**

Let’s not forget that the U.S. Food & Drug Administration *“Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide”* Section D clearly states that: **“It may not be possible always to draw a bright line between structure/function and disease claims.”** There will always be areas subject to interpretation, context and ever-changing definitions.

## **ONGOING CONCERNS:**

VitaPurity has repeatedly advised the FDA about several illegal businesses for the past nine (9) years on an annual basis. Yet no apparent action has been taken by the FDA in these cases. I have been amazed at the complete lack of concern shown by the FDA toward the illegal practices of these rogue companies and the threats they pose to the public at large.

VitaPurity is concerned that people suffering from life-threatening illnesses are being duped by rogue companies into buying ineffective and possibly unsafe products while legitimate companies like VitaPurity are not allowed to proclaim the medical benefits of our products to the public. ***People are dying that could be saved ... if only they knew about the medical uses and the medical power of certain natural substances.***

Even ***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.*** That's bad news for us and much worse news for the tens of thousands of cancer patients who have been given death sentences by their doctors, *i.e.* "You have 6 weeks to live and there is nothing more we can do for you". ***This brings me great pain since VitaPurity was originally developed to offer vital help to people suffering from cancer.***

If you have never experienced the loss of a loved one or heard the terrible words of death and hopelessness that doctors hand out like so many pieces of candy, you cannot understand the anguish, hopelessness, fear, loneliness, and the agony of knowing you will be leaving your loved ones. Try to think of them and consider the consequences of your actions when you go about silencing responsible companies that offer hope to the hopeless ... I'm talking about true, touchable hope, the kind of hope that VitaPurity is committed to giving all people, worldwide.

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## **FINAL COMMENTS:**

***VitaPurity continues to be cooperative, flexible and transparent with the FDA in spite of your agency's extreme scrutiny regarding the product descriptions on our website.*** VitaPurity hopes that one day the FDA will openly and publicly declare that we have strictly followed "truth in advertising", and that we have consistently used the highest-quality ingredients in the manufacture of our products that we humanly can.

VitaPurity continues to make compliance with the FDA our top priority while at the same time continuing to provide essential information to our customers. Because of the many FDA regulations that contradict other FDA regulations, it is a difficult and challenging endeavor to honor those guidelines while at the same time providing the vital information people need to make informed decisions when selecting the right nutritional supplements/alternative medicines.

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The changes VitaPurity has voluntarily made were based upon the information found under FDA regulation 21 CFR 101.93(g) with specific attention paid to section D: *“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.

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

VitaPurity has always, and will always do our best to inform and provide the general public (*our good customers*) with the very best and safest nutritional supplements available anywhere in the world.

To Your Health,

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