



U.S. Food and Drug Administration
Chicago District Office
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www.fda.gov

April 17, 2017

WARNING LETTER

CHI-5-17

UPS NEXT DAY
SIGNATURE REQUIRED

Intelligent Vitamin C, Inc.
Attn: Owen R Fonorow, President
24W500 Maple Ave Ste 107
Naperville, IL 60540-6056 US

The Vitamin C Foundation
Attn: Owen R Fonorow, President
24W500 Maple Ave Ste 107
Naperville, IL 60540-6056 US

Dear Mr. Owen R Fonorow,

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet address www.intelligentvitaminc.com in February 2017 and has determined that you take orders there for the following products: World's Finest Vitamin C Powder, Cardio-C, True Liposomal Vitamin C, Chewables Vitamin C, and Sodium Ascorbate. We have also reviewed your website at the Internet address www.vitamincfoundation.com, which provides a link to your website www.intelligentvitaminc.com where these products can be purchased directly. The claims on your websites establish that the products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:

On the page vitamincfoundation.org/alerts.php#ALERTS

Under #3. Vitamin C versus Cancer: Non-toxic "Chemo"

- Non-toxic "chemo" is the miraculous promise of "vitamin C" in the fight against cancer.

Under #4 Vitamin C is Anti-viral: High Doses do Cure the Common Cold

- "I tried your cold/flu therapy, and it works 100% like magic!"

- The effectiveness of vitamin C in preventing and relieving the symptoms of virus induced respiratory infections
- Vitamin C kills drug-resistant tuberculosis (TB) bacteria
- Vitamin C Protects Against the Ebola Virus

On the page vitaminfoundation.org/vitcancer.php

- Is Vitamin C a Miracle Cancer Cure? Yes and no. Non-toxic “chemo” is the miraculous promise of “vitamin C” in the fight against cancer.
- The ability of vitamins C, E, and selenium orally to prevent most cancers, and to decrease the mortality of pancreatic cancers, stomach cancers, prostate cancers and other cancers. The Vitamin C Foundation is interested in the how and why vitamin C prevents and treats cancers.
- Almost all vitamin C experts agree, hydrogen peroxide produced by high levels of ascorbate (vitamin C) kill cancer cells.
- Most experts recommend incorporating high-dose intravenous vitamin C (IV/C) infusions to achieve the high blood concentrations necessary to kill the most tumor cells.
- Vitamin C Foundation approved chewable vitamin C may contain Ewan Cameron’s Secret Weapon against cancer. (The chewable vitamin C is hyperlinked to a product listing which then takes consumers to intelligentvitamin.com)
- For maximum tumor-killing effect, intravenous vitamin C is recommended at dosages up to 200,000 milligrams (200 grams) per infusion, 2 or 3 times per week.
- Controversy: Does Vitamin C Work Inside or Just Outside of Cancer Cells? Probably both....the hydrogen peroxide created outside cancer cells kills them. Another camp believes that the oxygen redox levels inside cells (from massive amounts of ascorbate entering cancer cells) is what causes cancer cell death from apoptosis (cell suicide). This camp recommends intravenous vitamin C, but also recommends keeping the pressure on tumor cells with oral vitamin C to tolerance all day long.
- Case: Vitamin C Topically Cures Basal Carcinoma (Skin Cancer)

On the page vitaminfoundation.org/cardio.php

- In 1994 Lunes Payling, Ph.D, and his associate Matthias Rath, MD, patented LP(a) Binding Inhibitors for the prevention and reversal of common cardiovascular disease cause by a sub-clinical vitamin C deficiency...
- [H]igh-dose vitamin C treatment...for all forms of cardiovascular, disease, including congestive heart failure, heart disease and stroke

On a page vitaminfoundation.org/lipo.php

- True Liposomal Vitamin C may Exceed the Effectiveness of Intravenous Vitamin C (IVC) by a Factor of 10 treating infection
- Several doctors have reported to us that clinically, for certain conditions, especially viral infections and allergies, (and perhaps cancer, although this is controversial), true encapsulated liposomal may exceed the effectiveness of intravenous vitamin C.

On the page vitaminfoundation.org/www.orthomed.com/cancer.htm

- Vitamin C and Cancer. Pharmacologic ascorbic acid concentrations selectively kill cancer cells: Action as a pro-drug to deliver hydrogen peroxide to tissues
- Liposomal Dosage Recommendations
 - Viral Infections
 - Bacterial Infections
 - Heart Disease
 - Cancer

On the forums under vitamincfoundation.org/forum

- Examples of threads that promote your products to be used as drugs
 - A topic titled Vitamin C and Cancer with the description: This forum will be devoted to the study of ascorbate (high dose vitamin C) for the treatment of cancer
 - A topic titled Heart Disease and Stroke with the description: Answers to questions about Vitamin C and its relation to all forms of cardiovascular disease
 - A topic titled Infectious Diseases and Toxins with the description: Discuss vitamin C research and usefulness fighting infectious diseases and toxins, including the Swine Flu

Your vitamincfoundation.org/cardio.php webpage also contains evidence of intended use in the form of a personal testimonial recommending or describing the use of Cardio-C for the cure, mitigation, treatment, or prevention of disease:

- In Sept. 2007 I had to get a stent in my heart. I had one vein plugged 99% one 40% and one 60%. They put a stent in the 99% one, didn't do anything for the other two. In 2008, one year later they did a Cath. And found the other two clear after taking Cardio-C for one year.

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products World's Finest Vitamin C Powder, Cardio-C, True Liposomal Vitamin C, Chewables Vitamin C, and Sodium Ascorbate are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Furthermore, your products are intended for prevention of one or more diseases that are not amenable to prevention by consumers themselves without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, World's Finest Vitamin C Powder, Cardio-C, True Liposomal Vitamin C, Chewables Vitamin C, and Sodium Ascorbate fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction

or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. 331(a)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulations enforced by FDA.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which each such item will be corrected.

If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. Your written response should be sent to U.S. Food and Drug Administration, Attention: Lauren Crivellone, Compliance Officer, Food and Drug Administration, Chicago District Office, 550 W. Jackson Blvd., Suite 1500, Chicago, IL 60661. Refer to the Unique Identification Number (CMS# 514071) when replying. If you have any questions with regard to this letter, please contact Ms. Crivellone via email at lauren.crivellone@fda.hhs.gov or by phone at 312-596-4157.

Sincerely,



William R. Weissinger
District Director

Digitally signed by William R. Weissinger
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DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
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