

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# Strictly Health Corp 5/7/15



UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
BUREAU OF CONSUMER PROTECTION  
WASHINGTON, D.C. 20580

DEPARTMENT OF HEALTH  
AND HUMAN SERVICES  
FOOD AND DRUG  
ADMINISTRATION  
SILVER SPRING, MD 20993

## WARNING LETTER

**VIA EXPRESS MAIL**

MAY 7 2015

Anna McLean  
Strictly Health Corporation  
795 Commerce Drive UNIT 1  
Venice, FL 34292

Anna McLean  
Strictly Health Corporation  
8437 Tuttle Ave #403  
Sarasota, FL 34240

**Re: <http://www.fenvir.com>**

Dear Ms. Anna McLean:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses [www.fenvir.com](http://www.fenvir.com), [www.herpescuresinvestigated.com](http://www.herpescuresinvestigated.com), and [www.strictlyhealth.com](http://www.strictlyhealth.com) in March 2015 and has determined that you take orders there for the products FENVIR, Prosta Pep and Tonalin brand CLA. We have also reviewed your social media pages on Facebook, Tumblr, Pinterest, YouTube, and Twitter, which provide a link to your website at <http://www.fenvir.com>. Based on our review, your websites and social media pages” promote FENVIR, Prosta Pep and Tonalin brand CLA for conditions that cause these products to be 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)]. Further, we have reviewed your Fenvir product label and find that the product is misbranded within the meaning of section 403 of the Act (21 U.S.C. § 343).

### **New Drugs**

The therapeutic claims on your web sites and social media pages establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introduction or delivering these products for introduction into interstate commerce for such uses violates the Act. You may find the Act and FDA regulations through links on FDA’s home page at [www.fda.gov \(http://www.fda.gov/\)](http://www.fda.gov).

Examples of some of the website claims found on [www.fenvir.com](http://www.fenvir.com) that provide evidence that your Fenvir product is intended for use as a drug include:

On the webpage titled, “FENVIR How it Works”:

- “The FENVIR remedy works by attacking the problem of hsv cold sores, genital herpes and shingles from four different angles...”
- “Studies of herpes patient populations show that daily use of the FENVIR treatment can significantly increase immune strength and drastically reduce cold sore and genital herpes reactivation rates – even in people who had minimal or no success with other oral and genital herpes “cures,” including acyclovir...”
- “[A]ll-natural remedy...that is available without prescription. This incredible remedy is an advanced and multifaceted herpes treatment that overwhelms and keeps the virus sealed and subdued – helping to keep it from coming to the surface to cause any more outbreaks... FENVIR can keep you outbreak free...”

- “[P]otent all-natural antiviral that helps to aggressively halt viral reactivation, transfer, and replication thereby reducing the rate **outbreaks** and outbreak-associated lesions – and lowering the chance of transmitting the virus to others.”

On the webpage titled, “Research & Ingredients”:

Amla (*Emblica officinalis*)

- “Exhibits strong anti-viral properties...”
- “Suppresses HSV 1 and HSV 2 infections...”
- “Kills several types of infectious bacteria...”
- “Increases the healing rate of infected wounds...”

Red marine algae (*gigartina skottsbergii*)

- “Exhibits a number of HSV controlling properties...”
- “Reduces the formation of HSV colonies...”
- “Displays strong broad spectrum antiviral...”

Organic fucoidan (*Undaria pinnatifida*)

- “Exhibits powerful inhibitory action again [sic] the herpes simplex virus...”

Maitake mushroom extract

- “Inhibits bacteria...”
- “Thwarts viruses...”
- “Suppresses the herpes virus...”

Chlorophyllin (from sodium magnesium chlorophyllin)

- “Inhibits carcinogens from binding to DNA...”

Lemon Balm (*Melissa officinalis*)

- “Treats herpes...”
- “Fights infections...”

On the webpage titled, “FENVIR Frequently Asked Questions”:

- “What is the chance I will pass the virus to my partner?
  - o Taking a supplement like FENVIR herpes remedy that speeds healing, reduces viral shedding and prevents future outbreaks will help eliminate this risk.”
- “Does the FENVIR remedy treat both HSV-1 oral and HSV-2 genital herpes?”

- o Yes. It controls all forms HSV viruses, including HSV-1, HSV-2 as well the shingles (herpes zoster) virus. It is a newly formulated natural antiviral, made with ingredients that have shown to work against a broad spectrum viruses.”
- “How likely is this product to work for me if the ones my doctor gave me failed to help?
  - o Very likely. We’ve seen numerous instances where users had persistent sores and outbreaks despite using various prescribed treatments but later got the relief and results they wanted after starting FENVIR.”

The product label of FENVIR, located on the “Frequently Asked Questions” page, includes the following statement:

- o “Broad-Spectrum Antiviral...”
- o “Immunizing Antiviral Complex...”

Examples of some of the website claims found on your [www.herpescuresinvestigated.com](http://www.herpescuresinvestigated.com) website that provide evidence that your Fenvir product is intended for use as a drug include:

- “Powerful Anti-viral Properties...”
- “[T]he answer for anyone seeking to increase the healing rate and inhibit future outbreaks...effectively preventing frequent outbreaks and viral shedding.”

Examples of claims found on your [www.strictlyhealth.com](http://www.strictlyhealth.com) website that provide evidence that your FENVIR, Prosta Pep and Tonalin brand CLA products are intended for use as drugs include:

Fenvir Antiviral, noted on the homepage banner:

- “Heals existing HSV outbreaks within 72 hours...”
- “Prevents new outbreaks from occurring [sic]...”
- “Reduces Viral Shedding...”

Tonalin brand CLA product page:

- “Over 200 studies conducted worldwide indicates [sic] that when you take Tonalin CLA conjugated linoleic acid you are much less susceptible to diseases such as: breast cancer, asthma, heart disease, diabetes...”
- “[R]educe the incidence of breast cancer, improve asthma, allergy, blood sugar control and diabetes. It even limits atherosclerosis which can lead to heart disease!”
- “[R]educing cancer risk...”

Prosta Pep product page:

- “Defend Against Prostate Cancer...Lower PSA Score...”

- “[M]ay protect you from getting prostate cancer and may actually help you overcome prostate disease without having to undergo the use of dangerous drugs, debilitating and dangerous surgery, harmful radiation, and catastrophic microwave damage to your tissues...”
- “[S]hown to alleviate many of the symptoms of an enlarged prostate, which can lead to cancer!”
- “[R]elated symptoms including impotency...”
- “Beta-sitosterol (Found in Prosta Pep) also has cholesterol-lowering activity.”

In addition, there are claims on your Facebook, Tumblr, Pinterest, and Twitter social media pages, which have a link to your website at <http://www.fenvir.com> where your Fenvir product can be purchased directly. Further, your YouTube social media page provides a link to <http://bit.ly/natural-cure-herpes>, which redirects to your [www.fenvir.com](http://www.fenvir.com) website where your Fenvir product can be purchased directly. The claims on these social media pages provide further evidence that your Fenvir product is intended for use as a drug:

On Facebook: [[https://www.facebook.com/fenvirherpescure/info?tab=page\\_info](https://www.facebook.com/fenvirherpescure/info?tab=page_info)]  
 [<https://www.facebook.com/pages/Fenvir-Antiviral/130305067161579>]

- “FENVIR Advanced Broad-Spectrum Antiviral Treatment...”
- “FENVIR remedy works by attacking the problem of hsv cold sores, genital herpes and shingles from four different angles...”

On Twitter: [<https://twitter.com/fenvirantiviral>]

- “FENVIR Antiviral HSV #Herpes, Cold Sores & Shingles Treatment...”
- “FENVIR Broad Spectrum Antiviral...find your natural cure herpes...”

On YouTube: [<http://youtu.be/BxANFUvL3n8>]

- “You will need a treatment that will get to the source of your virus...” (3:01)
- “The Best All-Natural Anti-Viral...” (3:16)
- “There’s only one treatment that offers a multi-faceted attack on herpes virus... This amazing product is called FENVIR...” (3:20)

On Tumblr: [<https://www.tumblr.com/search/fenvir>]

- “FENVIR...remedy functions attacking the challenge of hsv fever blisters, herpes and shingles from four different angles...”

- “[F]ENVIR...can...drastically reduce cold sore and herpes reactivation rates...”

On Pinterest: [<https://www.pinterest.com/fenvir1/>]

- “The FENVIR remedy works by attacking the problem of hsv cold sores, genital herpes and shingles from four different angles.”
- “FENVIR Advance Broad Spectrum Antiviral Treatment...”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the 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 section 505(a) of the Act [21 U.S.C. § 355(a)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. 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.

Furthermore, your FENVIR, Prosta Pep and Tonalin brand CLA products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, these drugs are misbranded within the meaning of section 502(f)(1) of the Act, in that their labeling fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)]. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

### **Misbranded Dietary Supplement**

Your product is labeled to be a dietary supplement and is therefore subject to the requirements of section 403 of the Act and its implementing regulations. Our review revealed the following violations of section 403:

1. Your Fenvir product label is misbranded within the meaning of Section 403(y) of the Act [21 U.S.C. § 343(y)] in that the label fails to bear a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.
2. Your Fenvir product is misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] because the label fails to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient extract in the product is derived, as

required by 21 CFR 101.4(h)(1). For example, your product label declares “Prunella vulgaris 4:1 botanical extract and Amla (*Embllica officinalis* std. to 20:1 *Phyllanthus emblica* extract) as ingredients; however, the label fails to list the parts of the plant from which each botanical extract is derived.

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 FD&C Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials for all of your products to ensure that the claims you make for your products are not in violation of the FD&C Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to implement lasting corrective action of these violations may result in regulatory action being initiated by FDA without further notice. The FD&C Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products.

Please notify this office in writing within 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. You may respond in writing to Tyra S. Wisecup, Compliance officer, at Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740. If you have any questions concerning this letter, please contact Ms. Wisecup at (240) 402-5854.

### **Unsubstantiated Advertising**

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 300,303 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), *aff'd*, 356 Fed. Appx. 358 (11th Cir. 2009);

FTC v. Natural Solution, Inc., No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75,866, 2007 U.S. Dist. LEXIS 60783, at \*11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See In re Daniel Chapter One, No. 9239, 2009 WL 516000 at \*17-19 (F.T.C. Dec. 24, 2009), aff'd, 405 Fed. Appx. 505 (D.C. Cir. 2010).

The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers. Please notify FTC via electronic mail at [healthproducts@ftc.gov](mailto:healthproducts@ftc.gov) (<mailto:healthproducts@ftc.gov>) within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact David K. Koehler at 202-326-3627.

Sincerely,

/S/

Mary K. Engle

Associate Director

Division of Advertising Practices

Federal Trade Commission

/S/

William A. Correll

Director

Office of Compliance

Center for Food Safety

And Applied Nutrition

Food and Drug Administration

**More in 2015**

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