U.S. FOOD & DRUG ADMINISTRATION

FTC

# WARNING LETTER

**VIA OVERNIGHT DELIVERY**
**RETURN RECEIPT REQUESTED**

January 11, 2018

Ryan Donnelly
361 Memorial Pkwy
#525
Phillipsburg, NJ 08865

**RE: 542734**

Dear Mr. Donnelly:

This is to advise you that in December 2017 the U.S. Food and Drug Administration (FDA) reviewed your websites at the Internet addresses www.calmsupport.com and www.vitaminsupport.com and has determined that you take orders there for the product, "CalmSupport." FDA also reviewed the product label for your "CalmSupport" product and your websites at the Internet addresses www.facebook.com/CalmSupport, www.freefromhell.com, and www.freefromhellblog.com. The claims on your websites and product label establish that this product is a drug 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 it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product 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. In addition, the Federal Trade Commission has reviewed your marketing claims for "CalmSupport" for potential violations of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Examples of some of the claims found on your product label and website that provide evidence that your product is intended for use as a drug include:

On the label for your "CalmSupport" product:

- "Opiate Withdrawal Aid Program"
- "Ease the symptoms of opiate withdrawal"

On your www.calmsupport.com website:

On your home page:

- "The CalmSupport Withdrawal Supplement has been created along with our 'Withdrawal Aid Lifestyle Program' for living a … life free of opiates."
- "soothe the symptoms of opiate withdrawal naturally"
- "CalmSupport may also help with … anxiety … insomnia"

On your "About Us" page:

- "After hearing thousands of recovering addicts ask me what they can do to help lessen their symptoms of withdrawal … I decided to take the natural steps to creating CalmSupport."

On your "Frequently Asked Question" page:

- "CalmSupport was formulated for Opiate Withdrawal Symptoms"

On your "Home Remedies For Withdrawal" page:

- "[H]elp ease opiate withdrawal symptoms"
- "Help lessen the withdrawal symptoms related to opioid use from painkillers and narcotics such as: Oxycontin, Percocet, Hydrocodone, Fentanyl, Vicodin, Codeine, Morphine, Demerol, Heroin, Methadone, Suboxone, Roxicodone, Dilaudid, Oxycodone, and more."

On your "The Benefits of CalmSupport Opiate Withdraw" page:

- The Page Name
- "CalmSupport … an 'opiate withdrawal aid supplement'"

Your www.calmsupport.com website has an embedded YouTube video titled, "CalmSupport Review: The Leading Home Remedy For Opiate Withdrawal," which also links to the video page on YouTube, www.youtube.com/watch?v=d0E-hzgic1U. This YouTube page links to your website, www.calmsupport.com, where your product can be purchased directly, and provides further evidence that your product is intended for use as a drug:

In the YouTube video description:

- "CalmSupport Review: The Leading Home Remedy For Opiate Withdrawal"
- "…[T]he best opiate withdrawal aid on the market."

Additional claims observed on your website's blog, www.calmsupport.com/blogs/news that provide evidence your product is intended for use as a drug, include the following:

In an August 12th post on Page 149, titled, "What Can I Expect Going Through Opiate Withdrawal":

- " … [W]e at CalmSupport.com are here to help you the natural way. CalmSupport was formulated with the highest quality of organic ingredients, active vitamins, and

made specifically to help sooth withdrawal symptoms from opiates." [Aug 12, Page 149]

Also, claims made on your Facebook page, www.facebook.com/CalmSupport, which links to your website, www.calmsupport.com, where your product can be purchased directly, provide further evidence that your product is intended for use as a drug:

On your Facebook "About" page, accessible at https://www.facebook.com/pg/CalmSupport/about/:

- "The CalmSupport Opiate Withdrawal Aid Program is an all natural dietary supplement that has been created to help ease the withdrawal symptoms from opiate based pain killers."

On your website, www.vitaminsupport.com:

On your home page:

- "CalmSupport … Opiate Withdrawal Aid Supplement…Opiate withdrawal is less difficult with the symptom-easing ingredients this supplement offers."

Finally, we noted that your websites, www.freefromhell.com and www.freefromhellblog.com, include links to www.calmsupport.com, where your product can be purchased directly. Each of the websites includes claims that establish that your product is intended for use as a drug:

On www.freefromhell.com, under a link to purchase CalmSupport and the heading, "Home Remedies for Withdrawl *[sic]*:

- The Heading
- Are you ready to break free of your opiate addiction…Help ease the withdrawal symptoms from the use of opiate based pain pills such as: Percocet, Vicodin, Fentanyl, Demerol, Codeine, Morphine, Heroin, Methadone, Hydrocodone, Oxycontin, Suboxone, Dilaudid, Oxycodone and more."

On www.freefromhellblog.com, on the webpage, "Home Remedies for Opiate Withdrawal" accessible at www.freefromhellblog.com/home-remedies-for-opiate-withdrawal:

- "CalmSupport is one of the leading all natural supplements that may help reduce some of the withdrawal symptoms…"

Your product "CalmSupport" is not generally recognized as safe and effective for the above referenced uses and, therefore, this product is a "new drug" 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 and information demonstrating 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 product "CalmSupport" is intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for its intended purposes. Accordingly, "CalmSupport" fails to bear adequate directions for its intended uses and, therefore, the product is 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 misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your product. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

**Unsubstantiated Advertising**

In addition, the Federal Trade Commission has reviewed marketing claims related to opiate withdrawal and/or opiate addiction for "CalmSupport." The FTC Act requires that health-related claims, such as claims that a product will treat or cure a disease or other health condition, must be supported by competent and reliable scientific evidence at the time the claims are made. In other words, it is against the law to make health claims, whether directly or indirectly, through advertising, the use of a product name, website name, or any other means, without adequate scientific support, or to exaggerate the benefits of products or services you are promoting. **Violations of the FTC Act may result in legal action in the form of a Federal District Court Injunction or an Administrative Order and may require that you pay money back to consumers.**

Given the claims you are making, you should be aware of two FTC law enforcement actions challenging unsupported claims for the treatment of opiate addiction and/or opiate withdrawal symptoms: *FTC v. Sunrise Nutraceuticals, LLC*, which involved the product Elimidrol, and *FTC v. Catlin Enterprises, Inc.*, which involved the products Withdrawal Ease and Recovery Ease. The complaints and orders in those cases can be found at https://www.ftc.gov/enforcement/cases-proceedings/152-3208-x160006/sunrise-nutraceuticals-llc and https://www.ftc.gov/enforcement/cases-proceedings/1623204/catlin-enterprises-inc. The orders entered in both cases imposed monetary judgments and required the defendants to stop making deceptive claims.

The FTC strongly urges you to review all health-related claims that you and any of your affiliates are making in any medium. Competent and reliable scientific evidence for a product claiming to treat opiate withdrawal symptoms or opiate addiction consists of randomized, controlled, human clinical testing of that product. If any of your claims are not supported by competent and reliable scientific evidence, you should delete or revise them immediately.

With regard to the advertising claims discussed above, please notify Mamie Kresses of the FTC via electronic mail at mkresses@ftc.gov, within 15 working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. With regard to the FDA-related violations described in this letter, please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete corrective action within fifteen working days, please explain the reason for the delay and the date by which you will make the correction.

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 Compliance Officer Shawn Goldman at U.S. Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. If you have any questions concerning this letter, please contact Mr. Goldman at Shawn.Goldman@fda.hhs.gov.

Sincerely,

William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission