U.S. FOOD & DRUG ADMINISTRATION

FTC

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

January 11, 2018

Kenneth Nersten
Choice Detox Center, Inc. dba Nofeel
552 Hamilton Street
Suite E-1
Costa Mesa, CA 92627

900 E Katella Avenue Suite D
Orange, CA 92867-5035

RE: 543456

Dear Mr. Nersten:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.nofeel.com, in December 2017 and has determined that you take orders there for the product "Nofeel." The claims on your website establish that the 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 "Nofeel" 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 observed on your website that provide evidence your product is intended for use as a drug include the following:

- "Opiate Withdrawal Supplements"
- "Get the Best…Opiate Withdrawal Supplements…Clinically proven"
- "NOFEEL – "Opiate Withdrawal Supplements…you need to recover"
- "Nofeel system is a combination of formulas and functions…that work to achieve results."

Your product "Nofeel" 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 C.F.R. § 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 "Nofeel" 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 products safely for their intended purposes. Accordingly, "Nofeel" 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 this misbranded drug 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 "Nofeel." 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 fifteen 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

cc:
Domains by Proxy, LLC
14455 N. Hayden Road
Scottsdale, AZ 85260