U.S. FOOD & DRUG ADMINISTRATION

FTC

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

January 11, 2018

Soothedrawal, Inc.
Attn: David McDonald
Attn: Terrie McDonald
3330 Cobb Pkwy NW
Suite 324
Acworth, GA 30101

RE: 543430

Dear Mr. and Ms. McDonald:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address, www.soothedrawal.com, in December 2017 and has determined that you take orders there for your products "Soothedrawal Daytime Formula" and "Soothedrawal Nighttime Formula." FDA also reviewed your social media website at www.facebook.com/Soothedrawal. The claims on your websites establish that these 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 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 your "Soothedrawal Daytime Formula" and "Soothedrawal Nighttime Formula" products 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 products are intended for use as drugs include the following:

- "Beating addiction takes a strong desire to confront withdrawals and then a daily commitment to stay clean. Our natural opiate remedial detox products help smooth out the bumps along the way."
- "Soothedrawal Natural Opiate Withdrawal Remedial Products work directly to alleviate and soothe the symptoms of opiate withdrawal. Our proprietary treatment formulas use natural ingredients that specifically target and relieve the discomforts of acute withdrawals, both in the short term and long term. We help you get through the physical

symptoms of withdrawal and get on with your life."

- "Our step-by-step natural opiate withdrawal remedies fights off acute withdrawal symptoms and long term cravings. Use the Daytime and Nighttime Formulas the first 60 days, followed by the Extended Formula for up to a year to stay on a steady road to sobriety. Soothedrawal is real hope for success."
- "Acute withdrawal symptoms are eased by regular, daily doses of the Daytime Formula. This potent, proprietary blend helps the body heal and repair itself at a cellular level while helping combat joint pain, restless legs, nausea, chills/sweats, muscle spasms associated with opiate withdrawal. Our Daytime Formula is especially designed to work quickly in reducing the most acute withdrawal symptoms…"
- The website title: "Herbal Remedies for Opiate Withdrawal"
- "Soothedrawal is an all-encompassing herb-based product that is designed to help with opiate withdrawal without having to go and buy each one individually."
- "Amur Cork Bark…helps lower blood pressure and regulate blood sugars…"
- "…Soothedrawal offers both a Daytime and Nighttime Formula so you can ease the symptoms 24 hours a day. This can help you feel better as you go through the entire withdrawal process—naturally…"
- The website title: "Opiate Withdrawal Help"
- "Soothedrawal's Daytime and Nighttime Formulas is a great choice as it is designed to help you through the common mental and physical effects of opiate withdrawal in a soothing and natural way."
- "Opiate withdrawal isn't easy, but it is possible, especially when you use Soothedrawal."
- On the webpage titled, "Over the Counter Remedies for Opiate Withdrawal:" "For an all-in-one over the counter opiate withdrawal remedies, Soothedrawal offers both a Daytime and Nighttime Formula containing all-natural ingredients like vitamin B complex, ginger root, St. John's Wort, and magnesium citrate. Its specially designed formula is designed to provide relief from the anxiety, fatigue, and other common uncomfortable physical responses associated with opiate withdrawal."

Additionally, your website contains evidence of intended use in the form of personal testimonials recommending or describing the use of "Soothedrawal Daytime Formula" and "Soothedrawal Nighttime Formula" for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include the following:

On the webpage titled, "TESTIMONIALS & CLIENTS":

- "Would recommend this to anyone looking to get off Suboxone or Oxy. It worked for me."

On the webpage titled, "A MOTHER'S STORY":

- "My son started a 21-day taper process that included the Soothedrawal Daytime and Nighttime formulas…By incorporating the Daytime and Nighttime formulas into the tapering process, my son found that the withdrawal symptoms were reduced dramatically."

In the video titled, "Soothedrawal – Natural Remedies for Opiate Withdrawal Symptoms" featured on your website:

- The video title
- "Soothedrawal is an all-natural remedies *[sic]* for opiate withdrawal symptoms product used to treat opiate addiction."

We also note claims for your products on your Facebook page, accessible at www.facebook.com/Soothedrawal, which links to your website www.soothedrawal.com where your products can be purchased directly, provide further evidence that your products are intended for use as drugs. An example of these claims includes a June 15, 2015 post:

- "Soothedrawal help *[sic]* you get through the physical symptoms of withdrawal and get on with your life. Our line of opiate withdrawal treatments is designed to work together as a step-by-step process. It all begins by preventing (http://www.soothedrawal.com/products/) supplements for opiate withdrawal symptoms using the Daytime Formula in the morning and afternoon, and then taking the Nighttime Formula before going to bed."

Your products "Soothedrawal Daytime Formula" and "Soothedrawal Nighttime Formula" 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 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 products "Soothedrawal Daytime Formula" and "Soothedrawal Nighttime Formula" 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. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, "Soothedrawal Daytime Formula" and "Soothedrawal Nighttime Formula" fail to bear adequate directions for their intended uses 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 violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. 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 your "Soothedrawal Daytime Formula" and "Soothedrawal Nighttime Formula" products. 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

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:
Domain Protection Services, Inc.
P.O. Box 1769
Denver, CO 80201