U.S. FOOD & DRUG ADMINISTRATION

FTC

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

January 11, 2018

Bharati Pardasani
U4Life, LLC dba Mitadone
7000 Kennedy Blvd E
Apt 27C
West New York, NJ 07093

7002 Kennedy Blvd E
Apt 29 F
West New York, NJ 07093

RE: 542731

Dear Ms. Pardasani:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address, www.mitadone.com, in December 2017 and has determined that you take orders there for the product, "Mitadone Anti-Opiate Aid Plus Extra Strength." 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 "Mitadone Anti-Opiate Aid Plus Extra Strength" 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:

Mitadone Anti-Opiate Aid Plus Extra Strength

- The Product Name
- "Mitadone's proprietary formula … assist[s] the body and mind through the various stages of withdrawal."
- "GABA- Anxiety, insomnia and Addiction"

- "Chamomile- Fighting Anxiety and Depression"
- "May Help Ease Symptoms Associated with use of Painkillers, May Eliminate Cravings"
- "Mitadone Opiate Supplement May Help Ease Symptoms Associated with use of Painkillers"

Your website has an embedded YouTube video titled, "Mitadone Opiate Withdrawal Aid Review," which also links to the video page on Youtube, www.youtube.com/watch?v=Ear4hJFAERI. This YouTube page links to your website, www.mitadone.com, where your products can be purchased directly, and provides further evidence that your product, Mitadone Opiate Withdrawal Aid, is intended for use as a drug:

The YouTube video description:

- "Help ease withdrawal symptoms associated with use of Oxycontin, Morphine, Oxycodone, Opium, Vicodin, Demerol, Hydrocodone, Lorcet, Methadone, Suboxone, Heroin, Tramadol & other such Painkillers & Opioids. Helps eliminate cravings, symptoms & helps you quit."
- "Mitadone is to offer the best product on the market for opiate withdrawal symptoms"
- "Mitadone has shown to reduce the side effects resulting from a prolonged use of methadone and other opiates"

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

On the "Detox Center | Withdrawal Aid" post:

- The Post Name
- "Withdraw opioids safe with Mitadone"

On the "Withdrawal Aid | Opiate Withdrawal" post:

- The Post Name
- "MITADONE – OPIATE WITHDRAWAL AID SUPPLEMENT"
- "Mitadone is the most effective opiate withdrawal aid supplement … It is prepared to heal, detoxify and mitigate the withdrawal symptoms of Oxycontin, Morphine, Oxycodone, Opium, Vicodin, Demerol, Alcohol, Hydrocodone, Lorcet, Methadone, Suboxone, Heroin, Tramadol, etc."
- "try Mitadone which is especially formulated to aid and eliminate all the opiate withdrawal symptoms"

Your website contains evidence of intended use in the form of personal testimonials recommending or describing the use of Mitadone Anti-Opiate Aid Plus Extra Strength for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

On the Testimonials webpage:

- "I was prescribed Percocet … I tried to get off them but then I would get the typical tremors and sweats and I would always feel depressed … I decided to give [Mitadone] a try … It has been 2 weeks … and it has helped me stay off the Percocet."

- "I have used [Mitadone] continually for the past 3 months as I withdrawal from Tramadol … I took one Mitadone – 3 times a day … when I experienced withdrawal symptoms … The Mitadone has the right blend of vitamins, minerals and herbs needed to replace what an opiate drug causes the body to be deficient in. I generally didn't notice the reduced amount of Tramadol as long as I used Mitadone."

Your product "Mitadone Anti-Opiate Aid Plus Extra Strength" 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 "Mitadone Anti-Opiate Aid Plus Extra Strength" 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, "Mitadone Anti-Opiate Aid Plus Extra Strength" 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 "Mitadone Anti-Opiate Aid Plus Extra Strength." 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 Edward Glennon of the FTC via electronic mail at eglennon@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