



FTC

WARNING LETTER

**VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED**

January 11, 2018

Mr. Alessandro Pizzoccaro
President
GUNA, Inc.
3724 Crescent Court West
Whitehall, PA 18052

RE: 542995

Dear Mr. Pizzoccaro:

This is to advise you that the U.S. Food and Drug Administration (FDA) and the U.S. Federal Trade Commission (FTC) reviewed your website at <https://gunainc.com/>, from which you take orders for your GUNA-ADDICT 1 product. FDA has determined that your GUNA-ADDICT 1 product is intended to diagnose, mitigate, prevent, treat or cure opioid addiction. Your product is an unapproved new drug under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 355(a), and a misbranded drug under sections 503(b) and 502(f)(1) of the Act, 21 U.S.C. 353(b) and 352(f)(1). Introducing or delivering this product for introduction into interstate commerce violates section 301 of the Act, 21 U.S.C. 331. You may find the Act and FDA regulations through links on FDA's website at www.fda.gov. In addition, FTC has reviewed your marketing claims for GUNA-ADDICT 1 for potential violations of Sections 5 and 12 of the FTC Act, 15 U.S.C. 45(a) and 52.

Your firm's product, GUNA-ADDICT 1, is a drug under section 201(g)(1) of the Act, 21 U.S.C. 321(g)(1), because it is intended to diagnose, cure, mitigate, treat, or prevent disease, and/or intended to affect the structure or any function of the body. Examples of claims on your website that establish the intended use for GUNA-ADDICT 1 include, but may not be limited to, the following:

- "For the temporary relief of cravings, irritability, and inability to concentrate related to the use and over-use of: . . . Alcohol, Narcotics"

Your GUNA-ADDICT 1 product is also a new drug as defined by section 201(p) of the

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Act, 21 U.S.C. 321(p), because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Under section 505(a) of the Act, 21 U.S.C. 355(a), new drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA under section 505. No approved application pursuant to section 505 of the Act, 21 U.S.C. 355, is in effect for this product. Accordingly, the introduction or delivery for introduction into interstate commerce of this product violates sections 301(d) and 505(a) of the Act, 21 U.S.C. 331(d) and 355(a).

Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1), identifies criteria for determining the prescription status of a product. GUNA-ADDICT 1 is a prescription drug as defined in section 503(b)(1)(A) of the Act, 21 U.S.C. 353(b)(1)(A), because in light of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Therefore, this product is misbranded under section 503(b)(4) of the Act, 21 U.S.C. 353(b)(4), in that its label fails to bear the symbol, "Rx only."

GUNA-ADDICT 1 is intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. "Adequate directions for use" is defined in 21 CFR 201.5 as "directions under which the layman can use a drug safely and for the purposes for which it is intended." Because the conditions for which GUNA-ADDICT 1 is intended require the supervision of a practitioner licensed by law to administer such a drug, adequate directions cannot be written so that a layperson can use your product safely. Thus, your product's labeling fails to bear adequate directions for use, which causes the product to also be misbranded under section 502(f)(1) of the Act, 21 U.S.C. 352(f)(1). Section 301(a) of the Act, 21 U.S.C. 331(a), prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug.

The Acting Secretary of Health and Human Services, under section 319 of the Public Health Service Act, 42 U.S.C. 274d, has determined that a public health emergency exists nationwide involving the opioid crisis. The marketing and sale of unapproved opioid addiction treatment products is a potentially significant threat to the public health. Therefore, FDA is taking urgent measures to protect consumers from products that, without approval by FDA, claim to diagnose, mitigate, prevent, treat or cure opioid addiction.

We recognize that GUNA-ADDICT 1 is labeled as a homeopathic drug product with active ingredients measured in homeopathic strengths. The definition of "drug" in section 201(g)(1) of the Act, 21 U.S.C. 321(g)(1), includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drug products are subject to the same regulatory requirements as other drug products; nothing in the Act exempts homeopathic drug products from any of the requirements related to adulteration, labeling, misbranding, or approval. We acknowledge that many drug products labeled as homeopathic are manufactured and distributed without FDA approval under enforcement policies set out in the Agency's

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Compliance Policy Guide entitled, “Conditions Under Which Homeopathic Drugs May be Marketed (CPG 400.400)” (the CPG). However, the enforcement policies set forth in the CPG are not unlimited. The CPG states that it “delineates those conditions under which homeopathic drugs may *ordinarily* be marketed in the U.S.” The qualifying word “ordinarily” indicates that the CPG specifically contemplates that there may be circumstances where a product that otherwise may meet the conditions set forth in the CPG may nevertheless be subject to enforcement action.

As stated above, the Acting Secretary of Health and Human Services has determined that a public health emergency exists nationwide regarding opioid addiction and the consequences of the opioid crisis. A drug product labeled as homeopathic and marketed without FDA approval is not subject to the enforcement discretion set forth in the CPG when there is a nationwide public health emergency involving the disease that the product is intended to be used to diagnose, mitigate, prevent, treat or cure. Under these circumstances, the enforcement policies set forth in the CPG do not apply to GUNA-ADDICT 1, regardless of its homeopathic status.

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 all requirements of federal law and regulations. You should take immediate 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 GUNA-ADDICT 1. 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->

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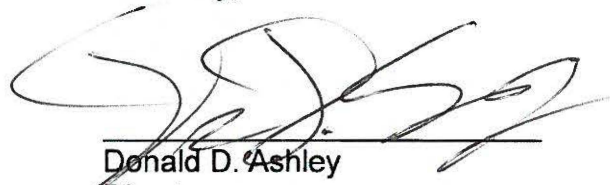
[x160006/sunrise-nutraceuticals-llc](#) and <https://www.ftc.gov/enforcement/cases-proceedings/1623204/catlin-enterprises-inc>. The orders entered in each case imposed monetary judgments and required the defendants to stop making deceptive claims.

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.

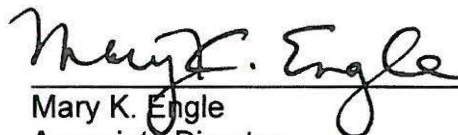
With regard to the advertising claims discussed above, please notify Mamie Kresses of the FTC via electronic mail at mkresses@ftc.gov within 15 working days of receipt of this letter of the specific actions you have taken to address FTC's concerns.

With regard to the FDA-related violations described in this letter, please notify FDA in writing, within 15 working days of receipt of this letter, of the specific steps that you have taken to correct those violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the FDA-related corrections. Your response regarding the FDA-related violations should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance, 10903 New Hampshire Avenue, WO51, Silver Spring, MD 20993-0002 or by email to FDAADVISORY@fda.hhs.gov.

Sincerely,



Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration



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