U.S. FOOD & DRUG ADMINISTRATION

FTC

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

June 7, 2018

William Houck
Up-Inya Beverages, LLC
22 Centennial St.
Fairfield, PA 173201
WilliamHouck@UpinyaBeverages.com

RE: 553138

Dear Mr. Houck:

This is to advise you that in January 2018, and again in February 2018, the U.S. Food and Drug Administration (FDA) reviewed your websites at the Internet addresses www.crossroads2freeedom.com and www.upinyabeverages.com and has determined that you take orders there for the "Crossroads Wellness Beverage" product. FDA also reviewed the product label for your "Crossroads Wellness Beverage" product. 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 FD&C 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 FD&C Act. You may find the FD&C 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 "Crossroads Wellness Beverage" 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 websites that provide evidence that your product is intended for use as a drug include:

On the label for your "Crossroads Wellness Beverage" product:

- "CROSSROADS was created specifically to pick you up. We've all been down before… life kicks everyone. Whether it's withdrawals, a big night out, or just feeling burned out in general. If you're at a crossroads in life and want a change – not just to survive, but to live again – try CROSSROADS.

On the "What is Crossroads?" page of www.crossroads2freeedom.com:

- "INTRODUCING CROSSROADS: After several years of testing with many different combinations of ingredients that help the symptoms of addiction withdrawal, we are excited to introduce Crossroads Wellness Beverage. Recovery from the stranglehold of opioids can be a costly and at times an unbearable process. Recovering addicts that have tried our product have rave reviews about their experience while taking Crossroads."

- "Crossroads is an addiction recovery beverage that helps detoxify, reduce withdrawals, and support recovering narcotics users."

On the "CROSSROADS WELLNESS BEVERAGE AND THE OPIOID EPIDEMIC" pages of www.upinyabeverages.com and www.crossroads2freeedom.com, under "The Journey to Crossroads…. The William Houck Story":

- "William Houck was an addict for 23 years. . . . He eventually got hooked on heroin and his addiction spiraled out of control, [sic] he was in and out of rehab for years. . . . [H]e decided that there must be a way for him and other drug addicts to get help using natural products and not prescription drugs. He worked with (5) chemist's [sic] for six months to come with the Crossroads formula specifically aimed to help addicts overcome the agony of going through withdrawals.

  In 2012, he went into relapse and found his life again being controlled by drugs. He had a case of Crossroads prototypes . . . and started taking it. Within fifteen minutes of his first drink he felt he was getting relief from the symptoms of withdrawal and the craving for the drug curved and eventually disappeared. He said that he went through the total withdrawal period without the anxiety, stress, headaches, diarrhea, and other pains that go along with withdrawals. He had several friends and families dealing with addicts to try [sic] the drink and they had similar results."

In written and video testimonials posted on the "What Our Customers are Saying" pages of www.upinyabeverages.com and www.crossroads2freedom.com:

- "I'm a recovering opiate addict and alcoholic and I drink 2 Crossroads a day to help with my anxiety, stabilize my mood and cut the cravings everyday [sic] to stay sober. I don't need pharmacotherapy or alot [sic] of the physc [sic] meds because I drink Crossroads."

- Testimonial video from Jerry Miller, Recovering Drug Addict: "[UpInya Beverages founder Bill Houck] said he had something to help me . . . . It was actually a drink called Crossroads. . . . I tried it and like 15 minutes later, leg cramps went away, upset stomach, diarrhea, restlessness, pacing back and forth – it all went away. I had no withdrawals at all."

- Testimonial video from Samantha T: "I was a heroin addict for about six years . . . . And then one day I found this product called Crossroads, and I started drinking that

instead of using heroin. And it took away my leg cramps. I can sleep. It took away my anxiety . . . and it made me feel better so I could stop using. And it really helped me change my life."

On the Crossroads Wellness Beverage Facebook page:

- "Crossroads is a wellness beverage that targets withdrawal symptoms from drug addiction. This could help so many. Please share. . . . #opiateaddiction #addictionsupport #treat #support #crossroadstorecovery #crossroads #upinyabeverage #recovery #drugaddiction #drugrehab #addictionhelp …

Your product "Crossroads Wellness Beverage" 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 FD&C 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 FD&C 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 FD&C 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 FD&C 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 "Crossroads Wellness Beverage" 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, "Crossroads Wellness Beverage" fails to bear adequate directions for its intended uses and, therefore, the product is misbranded under section 502(f)(1) of the FD&C 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 FD&C 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 FD&C 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 "Crossroads." 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 the claims made by you or your affiliates are not supported by competent and reliable scientific evidence, you should delete or revise them immediately.

If you believe that your products are not in violation of the FD&C Act or the FTC Act, include your reasoning and any supporting information for our consideration. 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