

December 8, 2017

The Honorable Scott Gottlieb  
Commissioner  
*and*  
Steven Tave, Director  
Office of Dietary Supplement Programs

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Gottlieb and Director Tave:

We write to provide the Food and Drug Administration (FDA) with troubling new information regarding eight products being sold as dietary supplements that purport to assist in the treatment of symptoms related to withdrawal from opioids.

We are also sharing this information with the Federal Trade Commission (FTC), in hopes that the FDA and FTC will work together so that: 1) the FDA prohibits the sale of these substances and others like them as unapproved and/or misbranded drugs under the Food, Drug and Cosmetic Act; 2) the FTC files charges against these companies for their false and/or unsubstantiated claims under the Federal Trade Commission Act; and 3) where possible, the FTC obtains refunds for purchases by consumers, as it was able to do in a recent similar case against Sunrise Nutraceuticals.<sup>1</sup>

We note that the FDA recently issued a public health advisory regarding products that contain kratom and are marketed as assisting with withdrawal associated with opioid addiction.<sup>2</sup> In addition, the FTC has publicized several recent cases regarding dietary supplements that were marketed as aids for opioid withdrawal.<sup>3</sup>

To understand this problem more fully, we conducted a brief market analysis in the last week of October and first week of November, examining products available for purchase online,<sup>4</sup> and identified eight products marketed as addressing the symptoms of opioid withdrawal and that did not contain kratom.<sup>5</sup> We then wrote to the manufacturers of each of these products to request evidence of their product's efficacy for this purpose.

As described in the attached addendum, the responses we received were often flip, cursory, riddled with pseudo-scientific jargon, or frighteningly ill-informed. None of the

companies produced—or even, evidently, attempted to produce—any adequate public scientific evidence. For example, the makers of one product, Mitadone Anti Opiate Aid Plus, replied:

We don't really have any scientific studies as such currently, it takes years & millions of dollars to do that however the product has been working to help ease symptoms for most people that have taken it along with their program, all we can say is proof is in the pudding. Hope the above was helpful. Have a pleasant week. Team Mitadone.

Similarly, the manufacturer of Opiate Detox Pro acknowledged that, “[s]cientific studies are very costly, so no, there is no study.” Three companies did not reply substantively or at all, including the maker of the Opiate Freedom Center Ultimate Recovery System, which was recently referred by the National Advertising Division, an industry self-regulatory body, to the FTC regarding false claims for its product.<sup>6</sup>

The opioid epidemic should be a top priority for both the FTC and FDA, and we appreciate Commissioner Gottlieb’s recent testimony in which he highlighted the need for promotion of medically-assisted treatment (MAT) for opioid addiction.<sup>7</sup> Unlike the products that are the subject of this letter, there are three FDA-approved medications for the treatment of opioid dependence; these treatments have been part of the opioid initiatives of both Secretaries Price and Burwell, as well as President Trump’s Commission on Combating Drug Addiction and the Opioid Crisis.

Opioid dependence is a disease and any product marketed for treatment of this disease must be an approved drug under federal law.<sup>8</sup> Unapproved products are also likely misbranded.<sup>9</sup> It is both outrageous and shameful that supplement manufacturers would seek to mislead patients and divert their efforts to overcome this devastating illness and their income toward entirely unproven remedies.

Moreover, the marketing of these products is violative of the FTC Act.<sup>10</sup> As Acting FTC Chairman Maureen K. Ohlhausen has said about similar unsubstantiated claims on dietary supplements not included in our survey that were marketed as assisting with opioid withdrawal, “People who struggle with this problem need real help, not phony claims and false promises...”<sup>11</sup>

We note that these substances meet the criteria for enforcement priority identified by FDA in guidance.<sup>12</sup> This guidance makes clear that enforcement regarding unapproved drugs will be a priority where such products “lack evidence of effectiveness.”<sup>13</sup> Moreover, claims on the products we identify herein are a primary example of “health fraud,” which the FDA defines in that same guidance as “[t]he deceptive promotion, advertisement, distribution or sale of articles . . . that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes.”<sup>14</sup>



The FDA's guidance further notes that it will prioritize indirect health hazard products (as defined in the guidance<sup>15</sup>) based on such factors as "whether the therapeutic claims are significant, whether there are any scientific data to support the safety and effectiveness of the product, and the degree of vulnerability of the prospective user group."<sup>16</sup>

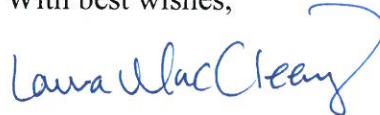
These products would, we suggest, readily qualify as enforcement priorities for the FDA under these criteria. In these eight cases, the therapeutic claims concern withdrawal from substances that, if continued to be administered, can lead to death or other serious risks. Furthermore, our inquiry of the companies shows that they generally lack data on effectiveness, despite their marketing claims. Moreover, one would be hard-pressed to identify a more vulnerable adult population—opioid addiction destroys lives and families, particularly among lower-income and more vulnerable populations,<sup>17</sup> and relapses can lead to imprisonment.<sup>18</sup> We suggest that these products should therefore be a high priority for action by the FDA.

Patients who purchase the products described in this letter may not avail themselves of the potentially lifesaving FDA-approved medications, as the FDA's recent public health advisory on kratom makes clear.<sup>19</sup> Substituting known and proven medically effective treatments for addiction with unstudied supplements is the very definition of health fraud and risks facilitating addiction and death.

We urge the FDA and FTC to issue immediate warning letters and bring enforcement actions that require cessation of sales of these and other such products and allow inspectors to seize products. We hope that the agencies will work together to ensure that these or other companies will not be able to continue to mislead patients and profit from these bogus claims, and to recover fair compensation for consumers who have been harmed.

We would be interested to speak with you at your convenience concerning our ongoing interest in monitoring the integrity, safety, and efficacy, of the supplement marketplace more generally.

With best wishes,



Laura MacCleery  
Director, Regulatory Affairs  
Center for Science in the Public Interest



## Notes

<sup>1</sup> “FTC Brings Action to Stop Marketer from Making Deceptive Opiate Addiction and Withdrawal Treatment Claims: Action Announced as Part of Joint Agency Dietary Supplement Sweep,” Nov. 17, 2015.

<https://www.ftc.gov/news-events/press-releases/2015/11/ftc-brings-action-stop-marketer-making-deceptive-opiate-addiction>

<sup>2</sup> “Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom.” Nov. 14, 2017. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584970.htm>.

<sup>3</sup> Aditi Jhaveri, “A sensitive subject,” Nov. 17, 2015, Federal Trade Commission blog post.

<https://www.consumer.ftc.gov/blog/2015/11/sensitive-subject>; FTC Brings Action to Stop Marketer from Making Deceptive Opiate Addiction and Withdrawal Treatment Claims: Action Announced as Part of Joint Agency Dietary Supplement Sweep, Nov. 17, 2015. <https://www.ftc.gov/news-events/press-releases/2015/11/ftc-brings-action-stop-marketer-making-deceptive-opiate-addiction>

<sup>4</sup> These were all of the products being marketed as helping with opioid addiction withdrawal that our researcher could then locate in an online search. CSPI then emailed each company, using its contact information, asking what scientific evidence it had to substantiate the claims each was making. Those who didn’t respond were emailed at least once again. Five eventually responded. Three did not. We have since identified one additional product that our researcher did not find at the time of the initial investigation: Restoritol (<https://www.ebay.com/itm/Restoritol-Opiate-Withdrawal-Aid-Natural-Supplement-2-Pack-180-Caps-total-/162588777620?hash=item25db0bdc94>), but we have not corresponded with this company.

<sup>5</sup> One product, Midatexone Opiate Withdrawal Aid, does not appear to currently be sold on Amazon.

<sup>6</sup> Press Release from the Advertising Self-Regulatory Council, “‘Opiate Freedom Center’ Fails to Respond to NAD Inquiry, Ad Claims for ‘Detox,’ ‘Withdrawal’ Referred to FTC,” Nov. 6, 2017. <http://www.asrcreviews.org/opiate-freedom-center-fails-to-respond-to-nad-inquiry-ad-claims-for-detox-withdrawal-referred-to-ftc/>

<sup>7</sup> Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for oral testimony before the House Committee on Energy and Commerce Hearing, “Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives,” Oct 25, 2017. <https://www.prnewswire.com/news-releases/remarks-from-fda-commissioner-scott-gottlieb-md-as-prepared-for-oral-testimony-before-the-house-committee-on-energy-and-commerce-hearing-federal-efforts-to-combat-the-opioid-crisis-a-status-update-on-cara-and-other-initiati-300543141.html>.

<sup>8</sup> It is a drug as defined by section 201(g)(1)(B)(C) of the FD&C Act, [21 U.S.C. § 321(g)(1)(B) and (C)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and intended to affect the structure or function of the body. It could also be classified as a “new drug” as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because this product is not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in its labeling.

<sup>9</sup> Under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act [21 U.S.C. § 321(n)], provides that, in determining whether an article’s labeling or advertising “is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations. . .”.

<sup>10</sup> The FTC may bring an action charging that marketing claims are false or unsubstantiated under Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), to obtain preliminary and permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendant’s acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

<sup>11</sup> “FTC Action Stops Unsupported Claims for Opiate Withdrawal Treatments: Defendants claimed herbal products alleviated symptoms of opiate withdrawal and helped users overcome opiate dependency,” May 4, 2017.

<https://www.ftc.gov/news-events/press-releases/2017/05/ftc-action-stops-unsupported-claims-opiate-withdrawal-treatments>

<sup>12</sup> Guidance for FDA Staff and Industry Marketed Unapproved Drugs. Compliance Policy Guide Sec. 440.100: Marketed New Drugs Without Approved NDAs or ANDAs. Sept. 19, 2011.

<sup>13</sup> *Id.*

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<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> Addressing the Opioid Crisis Means Confronting Socioeconomic Disparities, Oct. 25, 2017, National Institutes for Drug Abuse, <https://www.drugabuse.gov/about-nida/noras-blog/2017/10/addressing-opioid-crisis-means-confronting-socioeconomic-disparities>.

<sup>18</sup> “Court to Rule On Whether Relapse By An Addicted Opioid User Should Be A Crime,” *National Public Radio*, Oct. 26, 2017. <https://one.npr.org/?sharedMediaId=559541332:566877376>.

<sup>19</sup> “Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom,” Nov. 14, 2017. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584970.htm>.

