FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

January 24, 2018

Laura MacCleery
Director, Regulatory Affairs
Center for Science in the Public Interest
1220 L Street, NW, Suite 300
Washington, D.C. 20005-4053

Dear Ms. MacCleery:

Thank you for your December 8, 2017, letter expressing concerns regarding products, including dietary supplements, that purport to assist with the treatment of symptoms related to withdrawal from opioids.

The Food and Drug Administration (FDA or the Agency) shares your concern about these products, and one of FDA's highest priorities is to take whatever steps we can to reduce the scope and human tragedy created by the epidemic of opioid addiction. As you observed, FDA recently issued a public health advisory regarding kratom-containing products that are marketed to treat opioid withdrawal symptoms and opioid addiction. The Agency is committed to protecting consumers from products marketed in violation of the Federal Food, Drug, and Cosmetic Act, particularly those that may keep some patients from seeking appropriate care with proven treatments.

We are pleased to inform you that FDA has issued warning letters to eleven marketers and distributors of products that illegally claim to help treat opioid use disorder or are marketed as all-natural remedies for opioid withdrawal symptoms. Copies of these warning letters have been posted on FDA's webpage announcing enforcement actions.[1] This action was coordinated with our partners at the Federal Trade Commission.

The warning letters explain that the claims made on the products' websites demonstrate that the products are intended to be used to treat opioid use disorder. Opioid abuse is a serious public health issue, and FDA is concerned that unapproved products such as these may prevent individuals who are addicted to opioids from seeking treatments that have been proven to be safe and effective. Further, opioid abuse disorder requires proper diagnosis and oversight from a licensed health care practitioner, so it is impossible for a layperson to safely use the products for their intended purpose.

[1] https://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/ucm591295.htm

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Though the Agency cannot discuss specific details of any potential or ongoing investigations, we assure you that we take these matters very seriously.

Thank you again for contacting us regarding this important matter. Please let us know if you have any further questions or concerns.

Sincerely,

Steven J. Tave
Director
Office of Dietary Supplement Programs
Center for Food Safety
and Applied Nutrition