

DOCKET NO. DEA-442W

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

Scheduling of Mitragynine and 7-Hydroxymitragynine

December 1, 2016

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On August 31, 2016, the U.S. Drug Enforcement Administration (DEA) issued a notice of intent (the August 31 notice of intent) to temporarily schedule two constituents of the plant kratom (*Mitragyna speciosa*), mitragynine and 7-hydroxymitragynine, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). 81 FR 59929. AHPA submitted a letter to DEA in response to the August 31 notice of intent to ask that DEA consider the many comments being filed in this matter and initiate the regular scheduling process for these substances, if, in fact, warranted by scientific and medical evaluation of all of the factors that are required under the CSA to be considered in the regular scheduling process.

On October 13, 2016, DEA issued a Federal Register notice (the October 13 notice) in which it withdrew the August 31 notice of intent and solicited comments from the public regarding scheduling of mitragynine and 7-hydroxymitragynine under the CSA. 81 FR 70652. DEA also noted in the October 13 notice it had requested the Food and Drug Administration (FDA) expedite its scientific and medical evaluation and scheduling recommendation for mitragynine and 7-hydroxymitragynine, and that DEA had previously requested this information from FDA in accordance with 21 U.S.C. 811(b).

AHPA members market herbs and herbal products, and some members have previously included kratom ingredients in some of their products. AHPA and its members, including those that have previously marketed herbal products with kratom ingredients and those who market herbal products generally, have an interest in ensuring that any process that proposes to or considers scheduling an herb or herbal constituent includes a thorough evaluation of available scientific data and full consideration of potential risks and benefits of consuming the substance and the impact thereon associated with any scheduling. These comments are therefore submitted on behalf of AHPA and its members in response to the October 13 notice and its solicitation of comments.

DEA should generally refrain from directly or indirectly scheduling marketed plant articles

The CSA authorizes adding a drug or other substance to a schedule if that drug or other substance is found to have a potential for abuse, including, for example, potential for abuse as a stimulant or depressant drug or for any hallucinogenic effect. AHPA is not aware, however, of any instance in which a decision to add a substance to a schedule has had the effect of placing the restrictions associated with such scheduling on an article that is a plant or part of a plant, simply because that plant article contains the scheduled substance as a naturally occurring constituent.

As a general principle, AHPA is opposed to DEA using its scheduling authority in a manner that would have the effect of removing from the existing marketplace an herbal article simply because of the naturally occurring presence of one or more constituents that have become subject to scheduling under the broad standards established in the CSA. In AHPA's view, such scheduling would be an abuse of discretion.

AHPA understands kratom leaf to be widely used in the United States.¹ Since mitragynine and 7-hydroxymitragynine occur naturally in the leaf of kratom any placement of these naturally occurring contained constituents of kratom in any schedule under the CSA would have the effect of placing kratom leaf itself in the assigned schedule unless the scheduling process specifically exempts the unaltered leaf material. AHPA therefore encourages DEA to refrain from placing mitragynine or 7-hydroxymitragynine in any of the schedules under the CSA.

DEA should consider all available scientific information on health benefits and possible medical use

As part of DEA's scheduling process, the facts and science underlying consumption of mitragynine and 7-hydroxymitragynine will be examined to determine whether these substances meet the criteria for scheduling under the CSA. In the process of the scientific and medical evaluation of kratom's naturally occurring constituents mitragynine and 7-hydroxymitragynine DEA should consider not only information adverse to these constituents, but also any recognized health benefits or medical

¹ In the August 31 notice of intent DEA identified certain enforcement action taken by FDA against kratom-containing products through warnings to the public of health risks identified by that agency as associated with its use, seizure actions, and import alerts barring the import of such products into the United States. FDA has thus established that until the issues raised in those enforcement actions are resolved marketing of kratom-containing products in the U.S. is deemed unlawful.

uses of these compounds and the known health benefits and traditional uses of kratom leaf itself.

As a general matter, AHPA believes that in any consideration by DEA of placing a substance in any schedule under the CSA, and especially a substance that is a botanical ingredient or product currently or traditionally used for a recognized health benefit, DEA should abstain from any decision that would restrict future research that may discover new medical uses, health benefits, or other uses of the subject substance. AHPA believes such restrictions are not only contrary to the interests of science and industry but ultimately are also detrimental to the public interest.

AHPA greatly appreciates the opportunity to present comments on this matter and can be available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact me if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,



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