AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

September 30, 2016

Mr. Chuck Rosenberg
Acting Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Docket No. DEA-442 – Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I, Notice of Intent, 81 Fed. Reg. 59929 (Aug. 31, 2016)

Dear Acting Administrator Rosenberg:

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, including herbal dietary supplements. 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 to temporarily schedule mitragynine and 7-hydroxymitragynine into schedule I pursuant to the emergency scheduling authority of the Secretary of Health and Human Services and the temporary scheduling provisions of the Controlled Substances Act (CSA). These constituents are naturally occurring in the leaf of the plant species kratom (*Mitragyna speciosa*), such that DEA's Notice of Intent would have the effect of placing kratom leaf itself in schedule I upon the promulgation of a final order temporarily scheduling these substances.

AHPA urges DEA not to promulgate a final order temporarily scheduling mitragynine and 7-hydroxymitragynine into schedule I and to withdraw its August 31, 2016 Notice of Intent. Instead, AHPA asks that DEA: 1) consider the many comments that are being filed to this Docket by various organizations, and 2) 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.

Discussion

The Notice of Intent

In placing chemical constituents of kratom leaf temporarily into schedule I, DEA is required by the CSA to address only three of the eight factors required to be addressed for permanent scheduling. These three factors are the substance's history and current pattern of abuse (factor 4); the scope, duration and significance of abuse (factor 5); and what, if any, risk there is to the public health (factor 6). This is the information, along with notice to the Assistant Secretary of Health and the response thereto, upon which DEA may determine temporary scheduling of a substance in schedule I is necessary to avoid an imminent hazard to the public safety.

The CSA declares that a temporary scheduling determination is not subject to judicial review, an extraordinary provision that has been upheld by the Supreme Court. In addition, the Notice of Intent makes clear DEA's position that the temporary scheduling decision is not subject to the Administrative Procedure Act, the Regulatory Flexibility Act, or the Regulatory Planning and Review Executive Order. This is also extraordinary in present day regulatory systems. DEA has also concluded that temporary scheduling does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. If these positions are valid, such unfettered discretion to criminalize conduct and effectively obstruct the availability of historically marketed items of commerce must be exercised sparingly and with great care for the legitimate interests of affected persons.

The absence of opportunity to comment or for DEA to consider comments

In the present situation, DEA's assessments of the three factors necessary for temporary scheduling are based solely on limited and contradictory information of uncertain significance. Neither this information, nor DEA assessments, have been subjected to examination and considered in light of other information that might be presented in support of a contrary determination, since DEA has chosen a regulatory route that does not allow any additional information to be presented. For instance, in its analysis, DEA's factor 4 recitation of kratom's history and current pattern of use and abuse appears to have considered all use

of the material to constitute "abuse." This characterization should be open to examination and countering proofs, especially evidence of legitimate, non-abusive use. Similarly, DEA's factor 5 recitation of the scope, duration and significance of abuse accepts as true the information cited without providing the opportunity for citizens and medical professionals to examine the information fully. Moreover, much of the factor 5 analysis appears to be predicated on actions of the Food and Drug Administration, some of which remain in the administrative review process (which should be permitted to run their course) or were the subject of uncontested resolutions that did not involve any effort to test the assumptions on which they were based. The factor 6 analysis of the risk posed by kratom to the public health assumes the factual accuracy and relevance of adverse event and other reports without allowing the public and other professionals to scrutinize this information, which, after full scrutiny, may be shown to have been, at most, only peripherally involved.

AHPA fears that DEA is utilizing the CSA's imminent hazard temporary scheduling authority to criminalize kratom and thereby disable the public's right to effectively participate in an appropriate scheduling process. Because all of this is accomplished without considering the interests and needs of citizens who use kratom, consideration of these issues is missing from DEA's Notice of Intent.

The failure to consider the CSA's other schedule 1 factors

The CSA requires DEA to consider eight factors in determining whether to add a substance to Schedule 1 (21 U.S.C. 811(c)):

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

The three temporary scheduling factors are highlighted. However, where the evidence does not support a compelling need for immediate action, the five additional factors should also be considered before a substance that is widely

used by a non-abusing community is placed on schedule 1 and made criminal. These are the factors that must be considered in a full scheduling hearing and ought to be evaluated and subjected to full scrutiny prior to action, not after precipitously banning the substance.

An unacceptable precedent

The action declared in DEA's August 31, 2016 Notice of Intent with regard to constituents in kratom leaf is an unprecedented use of the emergency scheduling authority to temporarily place an herb into schedule I of the CSA. AHPA supports DEA's appropriate application of this emergency authority, which is regularly exercised by the agency, such that there are currently 20 substances listed in schedule I subject to temporary emergency scheduling (21 CFR 1308(h)). But these currently listed substances tend to be synthetic compounds, many of which are commonly known as "designer drugs" and are produced and marketed with no other purpose than as hallucinogens, illegal stimulants, and similar unlawful uses to "get high."

But none of the substances currently listed (or to the best of AHPA's knowledge, ever listed) in schedule I through the temporary listing mechanism is a simple herb, and DEA's temporary placement of mitragynine and 7-hydroxymitragynine in schedule I will have the effect of placing kratom leaf itself on schedule I.

This unprecedented application of the emergency authority for temporary placement of a substance on schedule I to an herbal ingredient with broad use is unacceptable. AHPA's view is that in situations involving an herb or other natural product DEA should reach out to herbal trade and professional associations prior to taking unilateral action that temporarily makes that herb unlawful. Indeed, in the present case there is an American Kratom Association that might have provided useful input to DEA's decision making process. Meeting or conferring with associations and groups is useful, appropriate and justified where such groups and associations are known to exist.

Conclusion

On the basis of the foregoing, AHPA respectfully requests DEA not to promulgate a final order temporarily scheduling mitragynine and 7-hydroxymitragynine into schedule I and to withdraw its August 31, 2016 Notice of Intent. Instead, AHPA asks that DEA: 1) consider the many comments that are being filed to this Docket by various organizations, and 2) 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.

Sincerely,

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