DOCKET NO. DEA-446

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

Schedule of Controlled Substances: Temporary Placement of Six Synthetic Cannabinoids Into Schedule I

February 7, 2017

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 January 9, 2017, the U.S. Drug Enforcement Administration (DEA or the Agency) issued a notice of intent (the January 9 notice of intent) to temporarily schedule six synthetic cannabinoids into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). The subject synthetic cannabinoids were identified in the January 9 notice of intent as: methyl 2-(1-(5-fluoropentyl)-1Hindazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMBPINACA]; methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; N-(adamantan-1-yl)-1-(5-fluoropentyl)-1Hindazole-3-carboxamide [5F-APINACA, 5F-AKB48]; N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1Hindazole-3-carboxamide [ADBFUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3,3-dimethylbutanoate [MDMBFUBINACA]. 81 FR 95395.[1]

The January 9 notice of intent notes the CSA and its implementing regulations are designed to prevent, detect, and eliminate diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. The January 9 notice of intent also notes Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with the authority to temporarily place a substance into schedule I for two years without regard to the requirements of 21 U.S.C. 811(b) if he/she finds that such action is necessary to avoid an imminent hazard to the public safety (citing 21 U.S.C.

[1] DEA issued a nearly identical notice of intent on December 21, 2016 but on January 9, 2017 issued a correction to this initial notice and simultaneously issued the January 9 notice of intent that is the subject of these comments.

811(h)), and that the Attorney General has delegated this authority to the Administrator of the DEA.

AHPA is aware that DEA has previously used its authority to temporary place numerous cannabinoids into schedule I, including at the least a final order issued on March 1, 2011 (five synthetic cannabinoids); a final order issued on January 30, 2015 (three synthetic cannabinoids); and a final order issued on February 5, 2016 (one synthetic cannabinoid).[2]

AHPA and its members and other companies that market herbal products have an interest in protecting the public from illicit substances marketed as synthetic cannabinoids and ensuring that DEA appropriately uses its CSA temporary scheduling authority. These comments are, therefore, submitted on behalf of AHPA and its members in response to the January 9 notice of intent and its solicitation of comments.

AHPA supports DEA's appropriate use of its temporary scheduling authority to place synthetic cannabinoids into schedule I

AHPA supports DEA's appropriate use of its authority under 21 U.S.C. 811(h) to temporarily place into schedule I substances that must be controlled to avoid an imminent hazard to the public safety. AHPA agrees, as DEA has stated in the January 9 notice of intent, that the synthetic cannabinoids listed in this notice, as well as synthetic cannabinoids generally, have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. AHPA therefore strongly supports DEA's use of its temporary scheduling authority to place synthetic cannabinoids, and specifically the six listed in the January 9 notice of intent, into schedule I.

DEA should refrain from scheduling marketed plant articles

On September 30, 2016, AHPA submitted a letter to DEA urging it not to promulgate a final order temporarily placing mitragynine and 7-hydroxymitragynine into schedule I and to withdraw its August 31, 2016 notice of intent in this matter. In its September 30 letter and in subsequent comments in this matter submitted on December 12,

[2] See 76 FR 11075 (March 1, 2011); 78 FR 28735 (May 13, 2013); 79 FR 7577 (February 10, 2014); 80 FR 5042 (January 30, 2015); 81 FR 6171 (September 6, 2016); and 81 FR 29142 (May 11, 2016).

2016, AHPA expressed opposition to the unprecedented use of DEA's emergency scheduling authority in a manner that would have the actual effect of temporarily placing an herb already broadly marketed into schedule I through placement in schedule I of constituents that are naturally occurring in that herb.

AHPA repeats here its view that DEA should refrain from using its temporary scheduling authority under 21 U.S.C. 811(h) to either directly or inadvertently place an herb into schedule I. If the Agency has made a determination based on scientific and medical evaluation of all of the factors that are required under the CSA that some such herb represents the risks that warrant scheduling, AHPA strongly encourages DEA to initiate the regular scheduling process for such a substance.

DEA should refrain from creating obstacles to health-benefit research

AHPA encourages DEA to evaluate any recognized health benefits or medical or traditional uses of any substance considered for placement in any schedule defined under the CSA, and especially a natural (non-synthetic) substance such as an herb or herbal constituent.

In addition and 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 natural substance currently or traditionally used for a recognized health benefit, DEA should take steps to prevent creation of unnecessary obstacles to future research that may discover new medical uses, health benefits, or other uses of the subject substance. AHPA believes such obstacles would be not only contrary to the interests of science and industry but ultimately also detrimental to the public interest.

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

Respectfully submitted,

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