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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-442W]

Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-Hydroxymitragynine into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice

ACTION: Withdrawal of Notice of Intent; Solicitation of Comments.

SUMMARY: On August 31, 2016, the Drug Enforcement Administration (DEA) published in the *Federal Register* a notice of intent to temporarily place mitragynine and 7-hydroxymitragynine, which are the main psychoactive constituents of the plant Mitragyna speciosa, also referred to as kratom, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. Since publishing that notice, DEA has received numerous comments from members of the public challenging the scheduling action and requesting that the agency consider those comments and accompanying information before taking further action. In addition, DEA will receive from the Food and Drug Administration (FDA) a scientific and medical evaluation and scheduling recommendation for these substances, which DEA previously requested.

DEA is therefore taking the following actions: DEA is withdrawing the August 31, 2016 notice of intent; and soliciting comments from the public regarding the scheduling of mitragynine and 7-hydroxymitragynine under the Controlled Substances Act.

DATES: The notice of intent that was published on August 31, 2016 (81 FR 59929) is withdrawn as of [INSERT DATE OF PUBLICATION]. The comment period will be open until December 1, 2016. All comments for the public record must be submitted electronically or in writing in accordance with the procedures outlined below. Electronic comments must be submitted, and written comments must be postmarked, on or before December 1, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. Please note that if you previously submitted a comment via email or regular mail following the August 31, 2016 notice, that comment is being considered by DEA – it is not necessary to resubmit the same comment *unless* you wish to provide additional information, or you wish to have your comment posted for public view in accordance with the instructions provided below.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-442W" on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking

Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this notice are considered part of the public record. If you previously submitted a comment via email or regular mail following the August 31, 2016 notice, that comment is being considered by DEA – it is not necessary to resubmit the same comment unless you wish to provide additional information, or you wish to have your comment posted for public view in accordance with the instructions provided below.

All comments received in response to this notice of opportunity to comment will, unless reasonable cause is given, be made available by DEA for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying

information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much personal identifying information or confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) or confidential business information included in the text of your electronic submission that is not identified as directed above as personal or confidential.

Background

Withdrawal of notice of intent

The Controlled Substances Act (CSA) contains a temporary scheduling provision, 21 U.S.C. 811(h), pursuant to which the DEA Administrator[1] may temporarily place a substance in schedule I where he finds that doing so is necessary to avoid an imminent hazard to the public safety. This provision of the CSA requires DEA to publish a notice in the Federal Register of its intent to issue a temporary scheduling order at least 30 days before issuing any such order. DEA published such a notice of intent on August 31, 2016, with respect to mitragynine and 7-hydroxymitragynine, which are the main psychoactive constituents of the plant commonly known as kratom. 81 FR 59929.

In response to the notice of intent, DEA received numerous comments from the public on mitragynine and 7-hydroxymitragynine, including comments offering their opinions regarding the pharmacological effects of these substances. To allow consideration of these comments, as well as others received on or before December 1, 2016, DEA has decided to withdraw the August 31, 2016 notice of intent published at 81 FR 59929. DEA has also requested that the FDA expedite its scientific and medical evaluation and scheduling recommendation for these substances, which DEA previously requested in accordance with 21 U.S.C. 811(b).[2]

[1] The Attorney General has delegated her functions under the CSA to the DEA Administrator.

[2] Section 811(b) provides that the scientific and medical evaluation and scheduling recommendation shall be conducted by the Secretary of Health and Human Services (HHS). This function has been delegated to the Assistant Secretary for Health. 58 FR 35460 (1993). Within HHS, the FDA has primary responsibility for conducting the evaluation and making the recommendation.

Accordingly, the August 31, 2016, notice of intent to temporarily place mitragynine and 7-hydroxymitragynine in schedule I is withdrawn. Mitragynine and 7-hydroxymitragynine therefore remain – as has been the case – noncontrolled substances under federal law.[3]

Consideration of public comments and FDA's analysis

With respect to mitragynine and 7-hydroxymitragynine, DEA will consider all public comments received under the above procedures, as well as FDA's scientific and medical evaluation and scheduling recommendation for these substances. Once DEA has received and considered all of this information, DEA will decide whether to proceed with permanent scheduling of mitragynine and 7-hydroxymitragynine, or both permanent and temporary scheduling of these substances.

Permanent Scheduling Process: As the CSA provides, if DEA determines that the medical and scientific facts contained in the FDA scheduling evaluation, along with all other relevant data and information, constitute substantial evidence of potential for abuse to support permanent scheduling of mitragynine and 7-hydroxymitragynine, DEA will publish in the Federal Register a notice of proposed rulemaking, which will give interested members of the public an additional opportunity to submit comments and request a hearing.[4] As provided in 21 U.S.C. 811(a), permanent scheduling rules shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by 5 U.S.C. 553, 556, and 557.

[3] Under some state and local laws, kratom and/or its constituents mitragynine and 7-hydroxymitragynine are currently listed as controlled substances or otherwise subject to control. Nothing in this publication alters the validity of such laws, or any pending state efforts to implement those laws or enact new laws controlling these substances.

[4] In permanent scheduling actions, when DEA reviews the FDA evaluation and scheduling recommendation, the FDA determinations as to scientific and medical matters are binding on DEA. 21 U.S.C. 811(b).

Temporary Scheduling Process: The pendency of permanent scheduling proceedings for a substance does not preclude a simultaneous or subsequent order to temporarily control that substance. If DEA finds in light of FDA's scientific and medical evaluation and after consideration of all public comments and other relevant information that, based on the criteria of section 811(h), temporary placement of mitragynine and 7-hydroxymitragynine in schedule I is necessary to avoid an imminent hazard to the public safety, DEA will follow the statutory procedures for issuing such a temporary scheduling order. As indicated above, before issuing such a temporary scheduling order, DEA would be required to publish in the Federal Register a new notice of intent.

Dated: October 6, 2016

Chuck Rosenberg,
Acting Administrator.
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