



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS-OASH-2026-0232]

Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I;
Request for Information

AGENCY: Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice; request for information; establishment of a public docket.

SUMMARY: The Office of the Assistant Secretary for Health (OASH or we) is opening a public docket to solicit input and comments on a proposed threshold for 7-hydroxymitragynine (7-OH) scheduling under the Controlled Substances Act. Public comments submitted to this docket will be provided by the Secretary for Health and Human Services for consideration by the Attorney General.

DATES: Submit either electronic or written comments, data, or information by July 31, 2026.

ADDRESSES:

Request for Information (RFI) Docket: You may examine the RFI docket at *regulations.gov* under HHS-OASH-2026-0232. The docket contains this RFI and all comments received to date. To submit a response, click the “Comment” button inside Docket: HHS-OASH-2026-0232 and follow all instructions.

FOR FURTHER INFORMATION CONTACT: Ruben Hernandez Segarra,

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SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the *Federal Register*, the Drug Enforcement Administration (DEA) has published a document entitled “Schedules of Controlled Substance: Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I.” In that

document, the DEA noted their intent to issue a temporary scheduling order (in the form of a temporary amendment) to add 7-hydroxymitragynine above a specified threshold, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, to schedule I under the Controlled Substances Act (CSA). The DEA's specified threshold for 7-hydroxymitragynine is as follows:

- (A) *Any botanical material of the plant *Mitragyna speciosa*, also known as kratom, and contains more than 0.050 percentage of 7-hydroxymitragynine on a dry weight basis, or*
- (B) *Any alternative article or material to that described in (A), that is:*
 - i. *Resulting from synthetic methods and containing 7-hydroxymitragynine present in amounts greater than 0.050 percentage weight/weight, weight/volume, or volume/volume or greater than 1.00 milligram of 7-hydroxymitragynine in the article, or*
 - ii. *Material derived from *Mitragyna speciosa* and further processed to manufacture alternative dosage forms such as extracts, concentrates, processed edibles, or pressed pills, and which may have materials that have been exposed to chemical, thermal, or other methods leading to chemical transformations that result in 7-hydroxymitragynine present in amounts greater than 0.050 percentage weight/weight, weight/volume, or volume/volume, or greater than 1.00 milligram of 7-hydroxymitragynine in the article.*

II. Topics for Public Input

This notice is seeking input on the 7-OH threshold identified and justified above. In particular, comments are sought on the following topics:

1. Whether any additional data exist that further support this or an alternative threshold level, and specifically, what concentration or quantity of 7-OH in a product constitutes an imminent hazard to public safety¹ and
2. Whether data exist supporting alternative measurement expressions for purposes of specifying the threshold level that is necessary to avoid an imminent hazard to public safety.

Note that OASH is not soliciting comment on any permanent scheduling decision, the general safety or utility of kratom-derived products, or other policy questions outside the scope of the threshold determination for temporary scheduling. Public comments submitted to this docket will be provided by the Secretary for Health and Human Services for consideration by the Attorney General.

Brian Christine

Assistant Secretary for Health, Department of Health and Human Services

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¹ The Controlled Substances Act (CSA) provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to public safety (21 U.S.C. 811(h)(1)). When issuing an order under 21 U.S.C. 811(h)(1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in 21 U.S.C. 811(c)(4), (5), and (6), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution (21 U.S.C. 811(h)(3)).