TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR subchapter F: biologics or other authority; information collection activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Part 680 (§§ 680.1–680.3); additional standards	NA	10	1	10	2	20
Section 402(j)(5)(B) of the PHS Act (42 U.S.C.); Certification to accompany biological product applications.	3,674	371	1	371	0.28 (17 minutes)	105
Total		371		70,946		860,170

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The numbers in this column have been rounded.

Noting that 5 CFR 1320.3(m) defines a recordkeeping requirement to include the reporting to the Federal government regarding such records, we have characterized the submission tasks reflected in Table 1 as reporting burden, assuming that respondents retain records in support of the respective submissions.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
601.6(a); Requirement to notify selling agents and distributors upon suspension of license.	1	20	20	0.33 (20 minutes) ..	7

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The number in this column has been rounded to the nearest whole number.

Based on our experience with the information collection, we account for disclosures under 21 CFR 601.6(a) distinctly, as reflected above in Table 2. Again, FDA assumes that respondents subject to regulatory requirements in 21 CFR 601.6 will retain corresponding records.

Cumulatively, these adjustments result in an average decrease of 2,168 responses and an average increase of 29,133 burden hours annually. We consider these nominal adjustments that reflect minimal change in the number of submissions and burden attributable to applicable requirements.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13533 Filed 7–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–4699]

Expedited Investigational New Drug Pilot Program; Request for Information; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 24, 2026. That notice opened a public docket to solicit input and comments on a proposal to establish a pilot program, the Expedited Investigational New Drug pilot program, to shorten the time it takes from drug identification to first-in-human study, while protecting clinical trial participants. FDA is correcting the email address of the document.

FOR FURTHER INFORMATION CONTACT: Benjamin Cook, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 2, Rm. 2114, Silver Spring, MD 20993–0002, 240–338–4685, *ExpeditedINDPilot@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 24, 2026 (91 FR 37996), in FR Doc. 2026–12621, the following correction is made:

On page 37997, in the third column, in the **FOR FURTHER INFORMATION CONTACT** section, the email is corrected to *ExpeditedINDPilot@fda.hhs.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13592 Filed 7–2–26; 8:45 am]

BILLING CODE 4164–01–P

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, *Ruben.HernandezSegarra@hhs.gov.*

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 safety [1] 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.

[FR Doc. 2026–13608 Filed 7–1–26; 4:15 pm]

BILLING CODE 4164–01–P

[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)).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request; Generic Clearance for NIH Citizen Science and Crowdsourcing Projects (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received by September 4, 2026.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Mikia Currie, Chief, Project Clearance Branch (PCB), Office of Policy and Extramural Research Administration (OPERA), Office of the Director (OD), Office of Extramural Research (OER), NIH, 6705 Rockledge Drive, Bethesda, Maryland 20892, MSC 7980, or call non-toll-free number (301) 435–0941 or Email your request, including your address to: *ProjectClearanceBranch@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection: Generic Clearance for NIH Citizen Science and Crowdsourcing Projects –0925–0766— exp., date 09/30/2026, EXTENSION, Project Clearance Branch (PCB), Office of Policy and Extramural Research Administration (OPERA), Office of the Director (OD), Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: Projects under this generic clearance will allow Agency researchers and program staff to test ideas more quickly, respond to the project's needs as they evolve, and incorporate feedback from participants for flexible, innovative research methods. The purpose of this information collection is to:

- Accelerate scientific research.
- Increase cost-effectiveness to maximize the return on taxpayer dollars.
- Address societal needs.
- Provide hands-on learning in STEM education.