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.