

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS¹—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	547	1.43	782	0.50 (30 minutes)	391
§ 312.160(c); shipper records of alternative disposition of unused drugs.	547	1.43	782	0.50 (30 minutes)	391
Subtotal			1,564		782
Total			43,451		2,832,742

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

While we have corrected an inadvertent calculation error pertaining to 21 CFR 300.200, we have otherwise retained the currently approved estimates attributable to IND requirements. We also note that reporting activities applicable to the “Right to Try” provisions began in 2020 and we continue to monitor the information collection activity.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–N–1560; FDA–2021–N–1351; FDA–2025–N–2549; FDA–2025–N–0426; FDA–2026–N–0746; FDA–2026–N–0497; FDA–2025–N–0953; FDA–2024–N–4467; FDA–2025–N–4942; FDA–2025–N–2195; FDA–2025–N–0354; FDA–2025–N–3215; FDA–2025–N–1108; FDA–2025–N–0419; FDA–2025–N–1210; FDA–2025–N–0414; FDA–2025–N–1115; FDA–2025–N–1109; FDA–2025–N–1330; FDA–2024–N–5943; FDA–2025–N–0351; FDA–2025–N–3656; FDA–2025–N–2220; FDA–2024–N–5890; FDA–2012–D–0429; FDA–2025–N–0348; FDA–2025–N–1812; FDA–2025–N–2548; FDA–2025–N–4348; FDA–2024–N–1055; FDA–2025–N–0615; FDA–2024–N–3762; FDA–2023–N–0894; FDA–2025–N–0308; FDA–2024–N–0668; FDA–2025–N–1732]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRASaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
Electronic Products Requirements	0910–0025	5/31/2029
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910–0045	5/31/2029
Investigational Device Exemptions	0910–0078	5/31/2029
Agreement for Shipments of Devices for Sterilization	0910–0131	6/30/2029
Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including API), and AMT Designation	0910–0139	7/31/2029
Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions	0910–0233	7/31/2029
Export of Medical Devices; Foreign Letters of Approval	0910–0264	3/31/2029
Prescription Drug User Fee Program	0910–0297	1/31/2029
Mammography Standards Quality Act Requirements	0910–0309	5/31/2029
Medical Devices; Humanitarian Use Devices	0910–0332	6/30/2029
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910–0339	5/31/2029
Food Safety, Health, and Diet Survey	0910–0345	3/31/2029
510(k) Third-Party Review Program	0910–0375	6/30/2029
Medical Device Reporting	0910–0437	2/28/2029
Postmarket Surveillance of Medical Devices	0910–0449	6/30/2029

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control number	Date approval expires
Guidance for Reagents for Detection of Specific Novel Influenza A Viruses	0910–0584	6/30/2029
Authorization of Medical Products for Use Emergencies	0910–0595	5/31/2029
Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization	0910–0607	6/30/2029
Electronic Submission of Medical Device Registration and Listing	0910–0625	4/30/2029
Tobacco Product Establishment Registration and Submission of Certain Health Information	0910–0650	4/30/2029
Tobacco Health Document Submission	0910–0654	4/30/2029
Current Good Manufacturing Practices for Positron Emission Tomography (PET) Drugs	0910–0667	6/30/2029
Testing Communications on Medical Devices and Radiation-Emitting Products	0910–0678	7/31/2029
Generic Drug User Fee Program	0910–0727	1/31/2029
Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products	0910–0731	4/30/2029
Center for Devices and Radiological Health Appeals Processes	0910–0738	6/30/2029
Q-Submission and Early Payor Feedback Request Programs and Medical Device Development Tools	0910–0756	5/31/2029
Animal Food and Egg Regulatory Program Standards	0910–0760	5/31/2029
Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act	0910–0800	5/31/2029
Medical Device Accessories	0910–0823	3/31/2029
Data To Support Social and Behavioral Research as Used by the Food and Drug Administration	0910–0847	5/31/2029
Generic Clearance for Quick Turnaround Testing of Communication Effectiveness	0910–0876	4/30/2029
Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities	0910–0883	3/31/2029
The Real Cost Monthly Implementation Assessment	0910–0935	3/31/2029
Emerging Drug Safety Technology Program	0910–0936	5/31/2029
Small Dispensers Assessment Under the Drug Supply Chain Security Act	0910–0937	6/30/2029

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7757]

Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA’s third-party disclosure and recordkeeping requirements for reportable food.

DATES: Either electronic or written comments on the collection of information must be submitted by October 16, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2026–N–7757 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential