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.

[FR Doc. 2026–16716 Filed 8–14–26; 8:45 am]

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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

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301796–8758, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Third Party Disclosure and Recordkeeping Requirements for Reportable Food—21 U.S.C. 350f

OMB Control Number 0910–0643—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), requires the establishment of a Reportable Food Registry (the Registry) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. Section 417 of the FD&C Act (21 U.S.C. 350f) defines ''reportable food'' as an ''article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.'' (See section 417(a)(2) of the FD&C Act.) We believe that the most efficient and cost-effective means to implement the Registry is by utilizing our electronic Safety Reporting Portal. The information collection provisions associated with the submission of reportable food reports have been approved under OMB control number 0910–0291.

In conjunction with the reportable food requirements, section 417 of the FD&C Act also establishes third-party disclosure and recordkeeping burdens. Specifically, we may require the responsible party to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(6)(B)(i) to (ii) of the FD&C Act). Similarly, we may also require the responsible party that is notified (*i.e.,* the immediate previous source and/or immediate subsequent recipient) to notify their own immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(7)(C)(i) to (ii) of the FD&C Act).

Notification to the immediate previous source(s) and immediate subsequent recipient(s) of the article of food may be accomplished by electronic communication methods such as email, fax, or text messaging or by telegrams, mailgrams, or first-class letters. Notification may also be accomplished by telephone call or other personal contacts, but we recommend that such notifications also be confirmed by one of the previous methods and/or documented in an appropriate manner. We may require that the notification include any or all of the following data elements: (1) the date on which the article of food was determined to be a reportable food; (2) a description of the article of food including the quantity or amount; (3) the extent and nature of the adulteration; (4) the results of any investigation of the cause of the adulteration if it may have originated with the responsible party, if known; (5) the disposition of the article of food, when known; (6) product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food; (7) contact information for the responsible party; (8) contact information for parties directly linked in the supply chain and notified under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act, as applicable; (9) the information required by FDA to be included in the notification provided by the responsible party involved under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act or required to report under section 417(d)(7)(A) of the FD&C Act; and (10) the unique number described in section 417(d)(4) of the FD&C Act (section 17(d)(6)(B)(iii)(I), (d)(7)(C)(iii)(I), and (e) of the FD&C Act). We may also require that the notification provides information about the actions that the recipient of the notification will perform and/or any other information we may require (section 417(d)(6)(B)(iii)(II) and (III) and (d)(7)(C)(iii)(II) and (III) of the FD&C Act).

Section 417(g) of the FD&C Act requires that responsible persons

maintain records related to reportable foods for a period of 2 years.

The congressionally identified purpose of the Registry is to provide a reliable mechanism to track patterns of adulteration in food which would support efforts by FDA to target limited inspection resources to protect the public health (see FDAAA, section 1005(a)(4)). The reporting and recordkeeping requirements described previously are designed to enable FDA to quickly identify and track an article of food (other than infant formula) for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals. We use the information collected under these authorities to help ensure that such products are quickly and efficiently removed from the market.

As required under section 1005(f) of FDAAA and to assist industry, we have issued the guidance entitled, ''Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007,'' which is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug.* The guidance contains questions and answers relating to the requirements under section 417 of the FD&C Act, including: (1) how, when and where to submit reports to FDA; (2) who is required to submit reports to FDA; (3) what is required to be submitted to FDA; and (4) what may be required when providing notifications to other persons in the supply chain of an article of food. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 7.46 of FDA's regulations have been approved under OMB control number 0910–0249.

Description of Respondents: Mandatory respondents to this collection of information are owners, operators, or agents in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States (''responsible parties'') who have information on a reportable food. Voluntary respondents to this collection of information are Federal, State, and local public health officials who have information on a reportable food.

We estimate the burden of this collection of information as follows:

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

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notifying immediate previous source of the article of food under section 417(d)(6)(B)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(6)(B)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Total	.....	.....	.....	.....	2,880

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

Third Party Disclosure: Although it is not mandatory under section 1005 of FDAAA that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification burden does not affect voluntary reporters of reportable food events.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—(mandatory reports).	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—(voluntary reports).	4	1	4	0.25 (15 minutes)	1
Total [2]	.....	.....	.....	.....	301

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

[2] For purposes of estimating number of records and hours per record, a ''record'' means all records kept for an individual reportable food by the responsible party or a voluntary reporter.

Recordkeeping: As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications for a period of 2 years. However, we do not expect that records will always be kept in relation to voluntary reportable food reports.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16714 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Request; 30-Day Public Comment Request; Submission for Office of Management and Budget Review; Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities

AGENCY: Office of the National Coordinator for Health IT, Office of the Secretary, HHS.

ACTION: Request for public comments.

SUMMARY: The Office of the National Coordinator for Health IT (ONC), Office of the Secretary (OS), Department of Health and Human Services, is seeking a three-year generic clearance to collect routine customer feedback on agency service delivery and program performance related to TEFCA.

DATES: Comments on the ICR must be received on or before September 16, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is, ''Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities''.

FOR FURTHER INFORMATION CONTACT: Talisha Searcy, *talisha.searcy@hhs.gov,* or call (240) 276–0642.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities.

Type of Collection: New Generic Collection.

Abstract: The Office of the National Coordinator for Health Information Technology (ONC) is seeking a three-year generic approval to collect routine customer feedback on agency service delivery related to TEFCA. ONC oversees a TEFCA Recognized Coordinating Entity® (RCE®) to administer aspects of TEFCA. The RCE is responsible for developing, implementing, and maintaining the Common Agreement that establishes the baseline technical and legal requirements for health information networks to share electronic health information. The data collections under this clearance will be designed to standardize monitoring and performance reports for TEFCA participants. With the number of TEFCA participants on the rise, ONC is seeking approval to collect this information from TEFCA users to enhance the efficiency of program management. In the **Federal Register** of May 11, 2026 (0990-New-60D), we published a 60-day notice requesting public comment on the proposed collection of information. We did not receive any comments in response to this notice. Thus, there were no modifications made to the content or burden hours estimated for this information collection.

Need and Proposed Use of the Information: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions and is not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into TEFCA users and stakeholder perceptions, experiences, and expectations; provide an early warning of issues with the service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communication between ONC and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. If this information is not collected, vital feedback from TEFCA users and stakeholders on the ONC services will be unavailable.

Likely respondents to the data collections under this generic clearance will be the Qualified Health Information Networks® (QHINs™), which are health information networks approved to access and exchange data through TEFCA. Over each of the next three years, an estimated 15 respondents are expected to participate, with approximately 7 qualitative feedback activities occurring annually and an average of 71 responses per respondent. The frequency of response will vary by activity, with each response taking an average of 80 minutes. This results in a total estimated burden of 1,420 hours annually, or 4,260 hours over a three-year period.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
QHIN	QHIN Application	15	1	3	45
QHIN	QHIN Monthly Report	15	12	2	360