administrative file the information that would form the basis of a decision on a matter under appeal, the submission of information as recommended in the guidance regarding the appeal request itself, as well as data and information relied on by the requestor in the appeal, will help facilitate timely resolution of the decision under review. We are accounting for burden respondents may incur as a result of these Agency recommendations in this collection request. Additional information about the CDRH appeals process is described in the companion guidance entitled ''Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff'' (March 2020), also available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a.*

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDRH Appeals Processes	75	1	75	8	504

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

Our estimated burden for the information collection reflects an overall increase of 320 hours and a corresponding increase of 40 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12419 Filed 7–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0615]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or 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 entitled ''Generic Clearance for Quick Turnaround Testing of Communication Effectiveness.''

DATES: Either electronic or written comments on the collection of information must be submitted by September 2, 2025.

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 September 2, 2025. 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–2025–N–0615 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRABranch@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.

Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

OMB Control Number 0910–0876—Extension

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role consumers and stakeholders play in ensuring the safety of the food supply, which helps ensure that suppliers produce food that meets U.S. safety standards. Section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes FDA to conduct food research and educational and public information programs relating to the safety of the nation's food supply.

This notice requests extension of OMB approval of the FDA information collection for a generic clearance that allows FDA to occasionally communicate with consumers and other stakeholders about immediate health issues which could affect public health and safety. This collection of information allows the use of fast-track methods of communication such as quick turnaround surveys, focus groups, and indepth interviews collected from consumers and other stakeholders to communicate FDA issues of immediate and important public health significance. We plan on using these methods of communication to collect vital public health and safety information.

For example, these methods of communication might be used when there is a foodborne illness outbreak, food recall, or other situation requiring expedited FDA food, dietary supplement, infant formula, or animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround information provided by this collection of information to help ensure its messaging has reached the target audience, has been effective, and, if needed, to update its communications during these events.

FDA plans to use the data collected under this generic clearance to test consumer or other stakeholder reaction to communications, advisories, and other educational messages under development or review when there are urgent public health matters requiring the dissemination of FDA communications. The tests will allow FDA to better understand consumers' responses, including behavior, knowledge, beliefs, perceptions, and attitudes to topics and concepts included in the communications. The data will not be directly used for the purposes of making regulatory or other policy decisions.

FDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per respondent) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;
- Personally identifiable information is collected by the contractor for their benefit only to the extent necessary, is not shared with FDA, and is not retained; and
- Information gathered will not be used for substantially informing influential policy decisions.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process. To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the survey, focus group or interview guide, and stimuli).

Respondents to this collection of information include a wide range of consumers and other FDA stakeholders such as producers and manufacturers of FDA-regulated food, infant formula, dietary supplements, and animal food and feed. Participation will be voluntary.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Indepth Interviews, Cognitive Interviews Screener ..	45	1	45	0.083 (5 minutes)	4
Indepth Interviews, Cognitive Interviews	9	1	9	1	9
Indepth Interviews Screener	300	1	300	0.083 (5 minutes)	25
Indepth Interviews	60	1	60	1	60
Survey Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
Survey Cognitive Interviews	9	1	9	1	9
Pretest survey screener	1,500	1	1,500	0.083 (5 minutes)	124
Pretest survey	300	1	300	0.25 (15 minutes)	76
Self-Administered Surveys—Study Screener	30,000	1	30,000	0.083 (5 minutes)	2,500
Self-Administered Surveys	6,000	1	6,000	0.25 (15 minutes)	1,500
Focus Group/Small Group, Cognitive Groups Screener.	180	1	180	0.083 (5 minutes)	15
Focus Group/Small Group, Cognitive Groups	60	1	60	1.5 (90 minutes)	90
Focus Group/Small Group Participant Screening	720	1	720	0.083 (5 minutes)	60
Focus Group/Small Group Discussion	240	1	240	1.5 (90 minutes)	360
Total	.....	.....	.....	.....	4,836

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

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

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12417 Filed 7–2–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–D–2335; FDA–2024–N–2888; FDA–2018–N–0180; FDA–2024–N–2149]

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 Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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 No.	Date approval expires
Food Labeling Regulations	0910–0381	4/30/2028
Substantial Equivalence Reports for Tobacco Products.	0910–0673	4/30/2028
Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications.	0910–0810	4/30/2028
De Novo Classification Process (Evaluation of Automatic Class III Designation).	0910–0844	4/30/2028
Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.	0910–0858	4/30/2028