4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0615]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 OMB control number for this information collection is 0910-0876. Also include the FDA docket number found in brackets in the heading of this document.

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, 301-796-8758, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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. One way the FDA supports these programs is through the use of this collection of information.

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 in-depth 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. 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.

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 has used this collection in the past three years by conducting quick turnaround surveys measuring communication effectiveness for the 2023 Salmonella Infantis Flour Recall, 2023 Hepatitis A Virus Infections/Frozen strawberry recall, and 2023 applesauce pouches recall. We also conducted food recall focus groups. This information gathered from these surveys and focus groups helped us understand how consumers and the public react to FDA communications messages and become aware of foodborne illness outbreaks and food recalls.

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.

In the *Federal Register* of July 3, 2025 (90 FR 29565), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1. --Estimated Reporting Burden[1]

Survey Type	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
In-depth Interviews, Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
In-depth Interviews, Cognitive Interviews	9	1	9	1	9
In-depth Interviews Screener	300	1	300	0.083 (5 minutes)	25
In-depth 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	7,500	1	7,500	0.083 (5 minutes)	622.5
Self-Administered Surveys	1,500	1	1,500	0.25 (15 minutes)	375
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					1,833.5

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

Since our initial request for continued approval, we have reevaluated actual usage of individual clearance requests. Accordingly, we have adjusted our estimate downward.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.
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