4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0430]

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 (PRA).

DATES: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Generic Clearance for Quick Turnaround Testing of Communication Effectiveness." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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-NEW

This notice announces the FDA information collection request to OMB for approval of a generic clearance that will allow FDA to use 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. 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, cosmetics, or animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround 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 will only submit individual collections for approval under this generic clearance if they meet 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 participant) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;

- Personally identifiable information (PII) is collected only to the extent necessary[1] and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;[2] and
- Information gathered will yield qualitative findings; the collections will not be designed or used as though the results are generalizable to the population of study.

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 an individual 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 moderator guide, or in-depth interviewing guide).

Individual collections will also undergo review by FDA senior leadership in the Center for Food Safety and Applied Nutrition, PRA specialists, and an institutional review board.

Respondents to this collection of information include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

In the *Federal Register* of April 2, 2019 (84 FR 12617), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

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[1] For example, collections that collect PII to provide remuneration for participants of focus groups, in-depth interviews, and cognitive laboratory studies will be submitted under this request. All privacy act requirements will be met.

[2] As defined in OMB and Agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

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

Table 1.--Estimated Annual 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	900	1	900	0.083 (5 minutes)	75
In-depth Interviews	180	1	180	1	180
Survey Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
Survey Cognitive Interviews	9	1	9	1	9
Pretest survey screener	750	1	750	0.083 (5 minutes)	62.25
Pretest survey	150	1	150	0.25 (15 minutes)	38
Self-Administered Surveys--Study Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys	15,000	1	15,000	0.25 (15 minutes)	3,750
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					10,881.25

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

This is a new collection of information whose total estimated annual burden is 10,881.25 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new individual survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: July 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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