United States Food and Drug Administration

Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

OMB Control No. 0910-NEW

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act, or the act) (21 U.S.C. 355) provides that FDA may take appropriate action to protect the public health when necessary. Further, the FD&C Act also authorizes FDA to conduct educational and public information programs (21 U.S.C. Section 393(d)(2)(D)). Moreover, Section 1003(d) (2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the FDA to conduct food research and educational and public information programs relating to the safety of the nation's food supply.

The Food and Drug Administration (FDA) sometimes needs to communicate with U.S. consumers and other stakeholders about issues of immediate and important public health significance such as 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 turn-around information collected from consumers and other stakeholders to help ensure its messaging has reached the target audience, has been understood and, if needed, to update its communications during these events.

FDA is requesting approval of this new generic, quick-turnaround clearance for collecting quantitative and qualitative information (i.e., surveys, focus groups, and in-depth interviews) to test communications or educational messages when there is an urgent public health need. FDA uses a variety of media messages and materials to inform and educate the public. Communicating effectively about these topics oftentimes involves conveying complex concepts. It is imperative for FDA to ensure that messaging is received and understood by the target audience.

FDA will submit individual collections under this generic, quick-turnaround clearance to OMB. Individual collections will have been cleared by senior leadership in the Center for Food Safety and Applied Nutrition, FDA Paperwork Reduction Act (PRA) specialists, and an Institutional Review Board. FDA will prepare a report during the OMB collection renewal summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance.

2. Purpose and Use of the Information Collection

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 (PII) 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.[1]

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 who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

3. Use of Improved Information Technology and Burden Reduction
4.
5. FDA will use Web-based data collection methods when collecting survey data and, wherever possible, in-depth interviews under this generic clearance. Using computer-assisted information technology to transmit data collection instruments and/or collect responses will continue to reduce the burden on participants as they will be able to access

[1] 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."

and respond to data collection requests at a time and place that is convenient to them, eliminating the need to travel for survey, focus group, or interview administration.

6. Web-based data collections are an especially convenient option for eliciting feedback on visual stimuli. With Web-based surveys, participants complete an on-line survey and then submit the data electronically over the Internet. Closed-ended questions (e.g., multiple-choice items, Likert scales) will be employed whenever possible. Web-based focus groups and in-depth interviews take advantage of the medium for conversation-based data collection. Similar to the advantages of web-based survey data collections, conducting web-based focus groups and in-depth interviews can reduce the burden on the respondent by allowing them to participate at a location convenient to them, increase sample diversity, and reduce cost to the government by allowing participation from across the U.S. and territories without incurring travel costs.

7.

8. FDA believes that 100% of the quantitative information collections and 25% of the qualitative information collections will be completed electronically.

9.

10. Efforts to Identify Duplication and Use of Similar Information

As new situations arise requiring quick-turnaround testing of FDA messaging, communications, advisories, or education because of a situation of urgent public health need, FDA will review existing reports of research on messages and materials to ensure that no data on the extant matter are being, or have been, gathered by FDA. Given that the need for communications feedback will be urgent and that the information collection will be based solely on current FDA communications, FDA does not expect that outside experts will have collected the data that FDA needs. However, FDA will work with other HHS operation divisions and other agencies responsible for communicating about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed with the public to ensure that duplicative data are not being gathered by them or are available from other sources known to FDA.

11. Impact on Small Businesses or Other Small Entities

Small businesses, or other small entities, may be involved in efforts related to collections of information approved under this clearance. However, FDA will minimize the effect and burden on them by sampling appropriately.

12. Consequences of Collecting the Information Less Frequently

During a public-health related event where FDA needs to communicate with consumers and other stakeholders the messaging oftentimes covers complex topics or is asking for an immediate public behavioral response (e.g., requests to discard contaminated items or to report adverse events). Without testing and data collections, FDA cannot fully ensure that these messages and materials have reached the target audience, are understood by them, and are serving their intended purpose – frequently seeking an immediate behavioral reaction (e.g., discarding the food).

13. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Studies under this collection rely on quantitative and qualitative methods and use convenience samples rather than probability samples. Therefore, the studies are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

14. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 4/2/2019 (84 FR 12617). No comments were received.

15. Explanation of Any Payment or Gift to Respondents

Gifts or payments offered to respondents as a token of the Agency's appreciation will be limited mainly to the cognitive interviews as FDA expects to use proprietary web-based panels that have their own methods for retaining participants for surveys. In the case of qualitative collections other than the cognitive interviews, instances for offering a small incentive will be addressed on a case-by-case basis (depending on the information collection design). FDA will provide a rationale in the justification memo for any studies that propose to offer incentives.

16. Assurance of Confidentiality Provided to Respondents

Information provided by participants will be kept secure to the extent allowable by law. Information about privacy will be communicated to participants by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to interviews, and consent forms. Participants also will be advised of the following: the nature of the activity; the purpose and use of the data collected; FDA sponsorship; and that participation is always voluntary. Because participation is voluntary, participants will be assured that there will be no penalties if they do not want to participate in the information collection as a whole or any part of the data collection.

Before data are collected, FDA researchers will obtain either an exemption or a full approval for all research from FDA's Institutional Review Board (IRB). Contractors are required to sign a pledge of privacy that reinforces privacy requirements of the study and states that any procedural violation that jeopardizes a respondent's privacy will be grounds for immediate termination and possible legal action.

All data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. Data will also be maintained consistent with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

This ICR does not request any personally identifiable information nor does it include a form that requires a Privacy Act Statement under section 5 U.S.C. §552a(e)(3)).

17. Justification for Sensitive Questions

There are no expectations that the individual projects will contain sensitive questions but if they do, FDA will include a justification for them in the individual submission.

18. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1 provides an estimate of anticipated burden levels that may be incurred during a 3-year period.

Table 1.--Estimated Reporting Burden[1]

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

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

The 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 estimated for projects to be conducted in the next 3 years. The number of respondents to be included in each new individual survey will vary, depending on the nature of the compliance efforts and the target audience.

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The average hourly compensation for this group is $24.34[2] To account for any overhead for this wage rate, we have doubled it to $48.68 to determine the cost to the potential respondents. The estimated annualized cost for the general public in this information collection for 10,881.25 hours of reporting time is $529,699.25. The number of respondents and length of response was determined on the basis of FDA's prior experience with communications testing and an estimate of the communication needs of the Center for Food Safety and Applied Nutrition. The actual numbers will vary depending upon the topic of interest.

Table 2: Annual Cost Burden Estimate

Survey Type	Total Burden Hours	Average Rate	Total Respondent Cost
In-depth Interviews, Cognitive Interviews Screener	4	$48.68	194.72
In-depth Interviews, Cognitive Interviews	9	$48.68	438.12
In-depth Interviews Screener	75	$48.68	3,651.00
In-depth Interviews	180	$48.68	8,762.40
Survey Cognitive Interviews Screener	4	$48.68	194.72
Survey Cognitive Interviews	9	$48.68	438.12
Pre-test survey screener	62.25	$48.68	3,030.33
Pre-test survey	38	$48.68	1,849.84
Self-administered surveys - Study Screener	6,225	$48.68	303,033.00
Self-Administered Surveys	3,750	$48.68	182,550.00
Focus Group/Small Group, Cognitive Groups Screener	15	$48.68	730.20
Focus Group/Small Group, Cognitive Groups	90	$48.68	4,381.20
Focus Group/Small Group Participant Screening	60	$48.68	2,920.80
Focus Group/Small Group Discussion	360	$48.68	17,524.80
Total	10,881.25	$48.68	$529,699.25

[2] U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, June 2018.

19. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

20. Annualized Cost to the Federal Government

Costs will include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, training interviewers, collecting and analyzing information, and reporting findings. Contractor expenses will vary from $40,000 to $110,000 depending on the size of the study. Therefore, in a given year, it is anticipated that approximately $900,000 in contractor expenses will be expended to fund at least two large scale studies and eight smaller scale studies.

In addition, government staff costs may be incurred for monitoring by the government Project Officer and Senior Analyst, projected to be about 25 percent of an FTE's time per year (522 hours). Given an FDA personnel cost for a GS-13, Step 1 is $47.52 per hour for 2019, and doubling this to $95.04 an hour to account for overhead, $49,610.85 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is $949,610.88 (which is equal to the total of contractor expenses ($900,000) plus FDA government staff salary cost ($49,610.88)).

21. Explanation for Program Changes or Adjustments

This is a new collection of information.

22. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

The process for conducting quantitative research includes the following steps: first, the problem is identified and then testing objectives are discussed, next the analytic questions to be addressed are determined. The procedures, instruments and data analysis plan will have been previously identified as the goal of these data collections is to use a bank of survey questions that have been pre-tested wherein just the subject of the urgent data collection need, the product, and the pathogen – if relevant – are inserted at the appropriate places in the questions. For the qualitative research, previously developed focus group moderator and interview guides will be adapted to current needs.

Analytic techniques for the survey will mainly comprise descriptive statistics, including percentages, cross-tabulations, and averages — presented along with demographic descriptions of study participants. Information collected from study participants may be subjected to subgroup analyses to uncover potential differences among key groups

(defined by gender, age, race/ethnicity, etc.). Inferential statistical analyses may also be conducted using cross-tabulation procedures with categorical variables (e.g., chi-square) and between-group procedures with continuous variables (e.g., ANOVA and t-tests). Parametric statistical tests will be used in the case of sufficient sample sizes, normal distributions, and continuous or interval data; nonparametric procedures will be used otherwise. All analyses will be done in the context of understanding the limitations of the data with respect to their not representing population parameters.

While the primary purpose of quantitative research is to provide information to FDA, FDA may make the results available to a variety of health educators at Government agencies, voluntary organizations, health professional organizations, and medical institutions. In addition, FDA may present the findings of its work at professional association meetings, including those of the American Public Health Association. Some results may be published in professional journals such as the *Journal of Public Policy and Marketing*. In any findings presented at professional association meetings or in professional journals, FDA will state the limitations of the data by recognizing its nonrepresentative nature.

The specifics of each study are not known. Because the materials will have been pre-developed, the data collection period should vary only by review and scheduling contingencies. Otherwise the typical survey is expected to conclude 3 days from notification of OMB clearance. A schedule for a typical data collection after identification of the need to collect data is shown below:

Adapt quick-turnaround pre-tested survey, or focus group/interview guide	2 days
Develop and submit OMB generic clearance request	3 days
Receive OMB clearance for Quick-turnaround project	5 days
Recruit participants and administer study	3-5 days
Compile results and report findings	2 days

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption from this requirement. The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.