U.S. Food and Drug Administration

Generic Clearance for Quantitative Testing for the Development of FDA Communications

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.

To ensure that communications activities and educational campaigns have the highest potential to be received, understood, and accepted by those for whom they are intended, FDA is requesting approval of this new generic clearance for collecting quantitative information (i.e., surveys, experimental studies) to test communications or educational messages on FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed while they are being developed or are in review. FDA uses a variety of media messages and materials to inform and educate the public about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Communicating effectively about these topics involves conveying complex concepts. Quantitative research is needed to assess the development, and continued relevance of, such messages given dynamic social and environmental factors and the changing education and information needs of the public.

Quantitative research aligns with Agency objectives. One of the eight science priority areas for FDA is to "strengthen social and behavioral science to promote informed decision-making about FDA-regulated products."[1] Quantitative research will play a large role in meeting this goal as it calls for identifying gaps in key areas of knowledge, reaching diverse audiences, assessing knowledge and perceptions about FDA-regulated products, evaluating the effectiveness of FDA's risk communication, and integrating knowledge from research and evaluation into practice.

[1] Food and Drug Administration. About Science & Research at FDA. Silver Spring, MD: U.S. Department of Health and Human Services (HHS), July 2013. Accessed from http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm342936.htm.

FDA will submit individual collections under this generic clearance to OMB. Individual collections will also undergo review by FDA's Research Involving Human Subjects Committee (RIHSC), senior leadership in the Center for Food Safety and Applied Nutrition, and Paperwork Reduction Act (PRA) specialists. 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

FDA plans to use the data collected under this generic clearance to test consumer reaction to communication and educational messages under development or review to better understand consumers' responses, including behavior, knowledge, beliefs, perceptions and attitudes to topics and concepts related to FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. 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 only to the extent necessary[2] and is not retained; and
- Information gathered will not be used for the purpose of substantially informing influential policy decisions.[3]
- Information gathered are intended to inform testing and pretesting of communication messages and other materials directed at consumers; and
- Information gathered are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

[2] For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.

[3] 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."

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 study instrument, experimental stimuli).

Respondents to this collection of information may 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 Information Technology and Burden Reduction

As computer technology has continued to improve and become more widespread, opportunities to implement Web-based data collection via the Internet have increased. Thus, wherever possible, FDA will make use of Web-based data collection methods when collecting quantitative data 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. For example, participants can access and respond to data collection requests at a time and place that is convenient to them, eliminating the need to travel for survey administration.

Web-based data collections, including those using experimental designs, 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.

FDA believes that at least 90% of the information collections will be completed electronically. Respondents to this collection will respond to this collection electronically.

4. Efforts to Identify Duplication and Use of Similar Information

As each new research study is developed, FDA will review existing literature and reports on existing messages and materials to ensure that no similar data are, or has been, gathered or maintained by FDA. FDA will also consult with outside experts to evaluate available information on similar messages with comparable audiences. FDA will work with other HHS agencies responsible for communicating about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed with the general public to ensure that duplicative data is not being gathered by them or are available from other sources known to FDA.

5. Impact on Small Businesses or Other Small Entities

There is no reason to believe that small businesses or other small entities will be impacted by efforts related to collections of information approved under this clearance.

6. Consequence of Collecting the Information Less Frequently

Because FDA uses a variety of media messages and materials to inform and educate the public about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed, quantitative research is needed to assess the development - continued relevance of - such messages, given dynamic social and environmental factors and the changing education and information needs of the public. Without quantitative testing and data collections, FDA cannot fully ensure that these messages and materials directed at consumers are serving their intended purpose. As a result, the FDA could spend a large amount of money on communications that are ineffective in achieving the intended purpose of reducing costs to people's lives and to the government.

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

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

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of September 4, 2018 (83 FR 44888). No comments were received.

9. Explanation of Any Payment or Gift to Participants

Gifts or payments offered to respondents as a token of the Agency's appreciation will be limited as FDA expects to use proprietary consumer web-based panels that have their own methods for retaining participants. If determined a necessity, instances for offering a small incentive will be addressed on a case-by-case basis (depending on the particular information collection design). Incentive amounts for information collections submitted under this generic will typically not exceed $20 for online surveys and $40 for in-person surveys involving populations that are difficult to recruit online. FDA will provide empirical evidence in the justification memo for any studies that propose to offer rates within and beyond this range.

10. Assurance of Confidentiality Provided to Participants

Information provided by participants will be kept private 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.

Communications testing efforts are typically reviewed by FDA IRB and are determined exempt from the "Regulations for the Protection of Human Subjects" in accordance with 45 CFR 46.101(b)(3) (Attachment 5). Before data are collected, FDA researchers will obtain either an exemption or a full approval for all research from FDA's Investigational Review Board (IRB), the Research Involving Human Subjects Committee. An independent contractor for FDA will collect the data and will not provide FDA with PII on the respondents. Respondents will be promised that their data will be treated as private and reported only in the form of aggregate statistics that cannot be associated with any individual or household. 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).

11. 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.

12. Estimates of Annualized Burden Hours and Costs

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

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive Interviews Screener	720	1	720	0.083 (5 minutes)	60
Cognitive Interviews	144	1	144	1	144
Pre-test study screener	2,400	1	2,400	0.083 (5 minutes)	199
Pre-testing study	480	1	480	.25 (15 minutes)	120
Self-administered surveys/experimental Studies Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys/Experimental Studies	15,000	1	15,000	.25 (15 minutes)	3,750
				Total	10,498

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

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The average hourly wages for this group is $24.34[4] The estimated annualized annual cost for the general public in this information collection for 10,498 hours of reporting time is $255,521.32. The number of participants and length of response was determined on the basis of FDA 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.

Survey Type	Total Burden Hours	Average Rate	Total Respondent Cost
Cognitive Interview Screener	60	$24.34	$1,460.40
Cognitive Interviews	144	$24.34	$3,504.96
Pre-test Study Screener	199	$24.34	$4,843.66
Pre-test study	120	$24.34	$2,920.80
Self-administered	6,225	$24.34	$151,516.50

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

surveys/experimental Studies Screener			
Self-Administered Surveys/Experimental Studies	3,750	$24.34	$91,275.00
Total			$255,521.32

13. Estimates of Other Total Annual Cost Burden to Participants or Record Keepers

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

14. 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 study 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 $36.24 per hour, and doubling this to $75.00 an hour to account for overhead, $39,150 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is $939,150 (which is equal to the total of contractor expenses ($900,000) plus FDA government staff salary cost ($39,150)).

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

The process for conducting quantitative research includes the following steps: first, the objectives are discussed, next the analytic questions to be addressed are determined, then the procedures, instruments and data analysis plan are developed. The analyses conducted for each quantitative study will be determined by the objectives, the data being

collected, and the characteristics of the participants. Specifics of the analyses cannot be determined until the survey instrument is developed.

Techniques include primarily quantitative analyses using descriptive statistics. Descriptive statistics — including percentages, cross-tabulations, and averages — will be calculated and 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 of the 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 the nonrepresentative nature of its pretests.

The specifics of each quantitative research study are not known at this time. While the data collection period varies somewhat depending on the complexity of the design and number of participants required, the typical study will require approximately 12 weeks from initial design to preparation of the report of findings. A schedule for a typical data collection is shown below:

Project Time Schedule

Activity	Time Schedule
Finalize materials	1 week after OMB approval
Finalize design	3 weeks after OMB approval
Collection of data	5 weeks after OMB approval
Analysis of data	10 weeks after OMB approval
Report	12 weeks after OMB approval

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

There are no exceptions to the certification.