

UNITED STATES FOOD & DRUG ADMINISTRATION

Quantitative Testing for the Development of FDA Communications
by the Center for Food Safety and Applied Nutrition (CFSAN)

GENERIC CLEARANCE

OMB Control No. 0910-0865 – Extension

Terms of Clearance: *Consistent with OMB approval, individual collection requests will continue to undergo review by FDA’s Research Involving Human Subjects Committee (RIHSC), senior leadership in CFSAN, and FDA Paperwork Reduction Act (PRA) specialists prior to submission. Also in accordance with OMB approval, we include a report summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance, in **Question 2** below.*

SUPPORTING STATEMENT – Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports educational and public information programs conducted by the Food and Drug Administration (FDA, the agency), as authorized under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)). The information collection also supports agency objectives pertaining to strengthening “*social and behavioral science to promote informed decision-making about FDA-regulated products.*”¹ To ensure that FDA communications and educational campaigns have the highest level of effectiveness, we intend to collect quantitative information to test communications and educational messages pertaining to products regulated by CFSAN during their review and development. FDA uses a variety of media to disseminate messages and materials to convey important and complex information about these products, which include foods, cosmetics, dietary supplements, and animal foods and feeds,. To help fulfill our public health protection mandate, we rely on quantitative research to assess the development, and continued relevance of, our communications in the context of changing social and environmental factors.

Quantitative research plays a large role in helping us identify possible gaps in the key areas of knowledge, reaching diverse audiences, assessing beliefs and perceptions about FDA-regulated products, and in evaluating the effectiveness of our risk communications. To facilitate submission and OMB review of the individual approvals requested under this clearance, we have developed a supporting documentation template to be completed and submitted along with the respective proposed collection instruments.

¹Food and Drug Administration. About Science & Research at FDA. Silver Spring, MD: U.S. Department of Health and Human Services (HHS), July 2013. Accessed from <https://www.fda.gov/science-research/advancing-regulatory-science/strategic-plan-regulatory-science>.

We therefore request extension of approval for the generic clearance discussed in this supporting statement, and administered in accordance with methodologies described in our supporting statement part B.

2. Purpose and Use of the Information Collection

Consistent with OMB communication on flexibilities under the PRA² and the use of Generic Clearance, individual submission requests will be those we believe are low in burden, similar in nature, and do not raise any substantive or policy issues. We intend to utilize the information collection as a way to test preliminary versions of communications we share with the public to help evaluate their clarity and usability. Consumer reaction and feedback to communications and educational messages under development will help us better understand current behavior, knowledge, beliefs, perceptions, and attitudes to topics and concepts related to FDA-regulated products. The data will not be directly used for the purposes of making regulatory or other policy decisions.

Since last OMB review and approval of the generic clearance, we have conducted the following individual information collections:

Title of Collection	Participants	Use of Information	Hours Used
Development and Improvement of FDA International On-Farm Readiness Review Training	150 respondent-trainees, including foreign government and university personnel, completed pre- and post-training tests.	Helps support safe produce initiative. More information can be found at: www.fda.gov/food/cfsan-constituent-updates/fda-commissioner-addresses-state-agriculture-commissioners-announces-new-steps-enhance-collaboration .	50
Agricultural Biotechnology Education and Outreach Initiative	6,000 solicitations resulted in 3,000 respondents (1500 control group, 1500 intervention group) who completed 2-wave survey.	Helps support directed outreach efforts. More information available at: www.fda.gov/food/agricultural-biotechnology/agricultural-biotechnology-education-and-outreach-initiative	2,000
Stakeholder Feedback Survey on CFSAN Outbreak and Response Evaluation Investigation Table	60 respondents from those electing to receive FDA updates on foodborne outbreak investigations completed survey.	Supports Coordinated Outbreak Response and Evaluation (CORE) initiative found at: www.fda.gov/food/outbreaks-foodborne-illness/about-core-network Updated weekly, we post information about foodborne illness outbreaks, even at early stages of an investigation when significant details are not yet known.	10

² [Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies \(July 22, 2016\)](#).

Title of Collection	Participants	Use of Information	Hours Used
Consumer Knowledge Regarding Agricultural Biotechnology and Biotechnology-Derived Food Products and Animal Feed-Study	*1,300 Spanish-speaking consumers recruited for survey.	*Collection underway to evaluate the efficacy of Spanish-language educational materials through a pre- and post-campaign study incorporating controlled exposure.	*917
TOTAL			0

3. Use of Improved Information Technology and Burden Reduction

As computer technology has continued to develop and become more widespread, opportunities to implement web-based data collection techniques 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 as well as facilitate processing by the agency. 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.

We believe at least 90% of the information collections will be completed electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. As each individual collection is developed, we review current scientific literature and other available data sources to avoid duplication of efforts and to maximize limited agency research funding. Also, as appropriate to the individual collection, we work with other HHS agencies engaged in similar or related research activities, and/or consult with outside experts that can potentially inform the agency's research objectives.

5. Impact on Small Businesses or Other Small Entities

No undue burden is imposed on small entities as a result of the information collection.

6. Consequences of Collecting the Information Less Frequently

We intend to administer the information collection consistent with identified agency needs and available resources. The date(s)/timing of an individual collection is communicated in Question 10 of the justification documentation memo submitted in support of our request.

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

Generally, studies under this clearance 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 the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of September 9, 2021 (86 FR 50544). Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore was not discussed in our 30-day notice of January 28, 2022 (87 FR 4625).

9. Explanation of Any Payment or Gift to Respondents

Gifts or payments offered to respondents as a token of appreciation will be limited as we expect to use proprietary consumer web-based panels with their own methods for retaining participants. Instances where offering a small incentive is determined necessary will be addressed on a case-by-case basis (depending on the particular information collection design). Incentive amounts for information collections conducted under this clearance will typically not exceed \$75, though more may be requested for difficult-to-recruit populations. In cases where FDA believes this is necessary, details and justifications for incentive requests will be provided.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This generic ICR will collect PII. This is a generic collection under which various studies to be conducted will first go through internal FDA PRA Staff and FDA Privacy Office review. The specific types of information collected may vary from study to study, but when PII is collected it typically consists of name and contact information.

PII is collected on behalf of the FDA by a contractor or vendor who conducts quantitative generic studies. PII is collected in the context of requesting individual feedback on the effectiveness of FDA communications and educational campaigns. Information collected by the vendor or contractor will be summarized into aggregate form, sent in aggregate to FDA (no PII will be included), and destroyed after the study or interview has been completed. Collected PII is used to notify potential respondents of their selection for an interview or study and include name and contact information. All individual information collected will be kept secure by the vendor or contractor. FDA and any vendor or contractor will disclose identifiable information only to the extent authorized by the individual or required by law. Contractors or vendors maintaining information will destroy all information in accordance with applicable records retention and other requirements per contract terms after the aggregate information has been provided to FDA and the study or interview has been completed. 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. In keeping with IRB/Human Subjects Research protocols, all the studies conducted under this approved generic collection obtained IRB clearance. The clearance process ensures that study data is appropriately secured (e.g., housed on the contractor’s servers, password protected, separate storage areas for each study, access controlled).

In most if not all cases, the Privacy Act will not apply to collected information. To ensure accurate determinations regarding Privacy Act application, the FDA Privacy Office will review the details of each study conducted under this generic collection approval. In instances when the Privacy Act applies, FDA will satisfy the requirements of the statute for the study at issue.

11. Justification for Sensitive Questions

We anticipate no sensitive questions will be included in the individual collection requests submitted under this generic clearance. In the event a question is proffered that may be regarded as sensitive, we will provide a justification and explain its relevance to the individual collection.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

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	0.25 (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	0.25 (15 minutes)	3,750
Total					10,498

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

Although respondents to the collection of information are private individuals, they will include a wide range of consumers and other FDA stakeholders, potentially including producers and manufacturers of FDA-regulated products.

12b. Annualized Cost Burden Estimate

Table 2.-- Estimated Annual Cost Burden

Survey Type	Total Burden Hours	Average Rate	Total Respondent Cost
Cognitive Interview Screener	60	\$27.07	\$1,624.20
Cognitive Interviews	144	\$27.07	\$3,898.08
Pre-test Study Screener	199	\$27.07	\$5,386.93
Pre-Test Study	120	\$27.07	\$3,248.40
Self-Administered Surveys/Experimental Studies Screener	6,225	\$27.07	\$168,510.75
Self-Administered Surveys/Experimental Studies	3,750	\$27.07	\$101,512.50
Total			\$284,180.86

As respondents to the information collection are private individuals from among a range of categories, we assume wage rates attributable to those across “*all occupations*” and multiply that figure by the annualized number of burden hours. [$\$27.07^3 \times 10,498 \text{ hours} = \$284,180.86.$] The number of participants and time needed for response was based on our prior experience with communications testing and an estimate of the communication needs of CFSAN. The actual numbers will vary depending upon the topic of interest.

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

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

14. Annualized Cost to the Federal Government

Costs to the Federal government 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. We anticipate allocating \$900,000 in contractor expenses to fund at least two large scale study and eight smaller scale studies annually.

In addition, we assume administrative costs for monitoring by a government Project Officer and Senior Analyst, or approximately ¼ 25 FTE’s per year (522 hours). Assuming 2022 wage rates of a GS-13/Step 1 employee in the Baltimore-Washington area, (\$51.18 per hour), and doubling this to account for overhead (\$102.36 per hour), we calculate administrative costs of \$53,432.

Cumulatively, therefore, we estimate a total of \$953,432 annually.

³U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, May 2020.

15. Explanation for Program Changes or Adjustments

Based on an evaluation of the information collection since last OMB review and approval, we have made no adjustments to our burden estimate. This relatively new generic clearance continues to be utilized. 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 survey will vary, depending on the nature of the compliance efforts and the target audience.

16. Plans for Tabulation and Publication and Project Time Schedule

17. 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, however we project the following schedule of activities:

18.

19. Activity	20. Time Schedule
21. Finalize materials	22. 1 week after OMB approval
23. Finalize design	24. 3 weeks after OMB approval
25. Collection data	26. 5 weeks after OMB approval
27. Analysis of data	28. 10 weeks after OMB approval
29. Report	30. 12 weeks after OMB approval

31.

32. 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.

33.

34. While the primary purpose of quantitative research is to gather information in support of agency initiatives, FDA may make study 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.

35.

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

The OMB expiration date will be displayed as required.

37. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.