United States Food and Drug Administration

Quantitative Testing for the Development of FDA Communications
by the Human Foods Program (HFP)

GENERIC CLEARANCE

OMB Control No. 0910-0865 – Extension

SUPPORTING STATEMENT

Terms of Clearance: FDA will submit individual collections under this generic clearance to OMB. Individual collections will also undergo review by FDA's Human Subject Protection Program, senior leadership in HFP, 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.

In accordance with OMB terms of clearance, we have included, as a supplementary document, a summary of gen ICs conducted under this umbrella generic ICR.

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), 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] This information collection for a generic clearance allows FDA to use quantitative social/behavioral science data collection techniques (i.e., surveys and experimental studies) to test consumers' reactions to FDA communications or educational messaging about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. 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, it is important to assess communications while they are under development. Understanding consumers' attitudes, motivations, and behaviors in response to potential communications and educational messaging plays an important role in improving FDA's communications.

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

- 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;

[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 https://www.fda.gov/science-research/advancing-regulatory-science/strategic-plan-regulatory-science.

- Personally-identifiable information (PII) is collected only to the extent necessary[2] and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;[3] and
- Information gathered will yield qualitative findings; the collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

To obtain approval for an individual generic collection submission 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 or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA's Human Subject Protection Program, senior leadership in HFP, and PRA specialists.

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 PRA[4] 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.

Description of Respondents: 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 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

[2] For example, collections that collect PII to provide remuneration for participants of surveys, experiments, and 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."

[4] Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies (July 22, 2016); available at https://www.whitehouse.gov/omb/information-regulatory-affairs/federal-collection-information/.

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 July 31, 2024 (89 FR 61453). No comments were received.

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 personally identifiable information (PII). This is a generic collection under which various studies to be conducted will first go through internal PRA Staff and 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 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 includes 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 it 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 obtain 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 2.--Estimated Annual Reporting Burden[1]

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 3.--Estimated Annual Cost Burden

Survey Type	**Total Burden Hours**	**Average Hourly Rate**	**Total Respondent Cost**
Cognitive Interview Screener	60	$31.48	$1,888.80
Cognitive Interviews	144	$31.48	$4,533.12
Pre-test Study Screener	199	$31.48	$6,264.52
Pre-Test Study	120	$31.48	$3,777.60
Self-Administered Surveys/Experimental Studies Screener	6,225	$31.48	$195,963.00
Self-Administered Surveys/Experimental Studies	3,750	$31.48	$118,050.00
Total			$330,477.04

As respondents to the information collection are private individuals from among a range of categories, we assume mean hourly wage rates attributable to those across "*all occupations*" and multiply that figure by the annualized number of burden hours. [$31.48[5] x 10,498 hours = $330,477.04.] 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 HFP. The actual numbers will vary depending upon the topic of interest.

[5] U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, May 2023.

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 studies and eight smaller scale studies annually.

In addition, we assume administrative costs for monitoring by a government Project Officer or Senior Analyst, or approximately 25% of an FTE's time per year (522 hours). Assuming 2024 wage rates of a GS-13/Step 1 employee in the Baltimore-Washington area, ($56.52 per hour), and doubling this to account for overhead ($113.04 per hour), we calculate administrative costs of $59,007.

Cumulatively, therefore, we estimate a total of $959,007 annually for costs to the Federal government.

15. Explanation for Program Changes or Adjustments

Based on an evaluation of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. 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

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:

Table 4.--Project Time Schedule

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

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 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, such as 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.

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

The OMB expiration date will be displayed as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.