

United States Food and Drug Administration

Generic Clearance for Qualitative Data to Support  
Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and  
Animal Food and Feed

OMB Control No. 0910-0891

SUPPORTING STATEMENT

**Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This generic information collection supports research 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. Section 393(d)(2)(D)). In addition to overseeing food and cosmetic products, dietary supplements, and animal food and feed, the Center for Food Safety and Applied Nutrition (CFSAN) also conducts studies to support communications with the public on these topics. To ensure that regulatory actions and communications activities have the highest potential to be received, understood, and accepted by those for whom they are intended, CFSAN and related FDA offices will conduct research and studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C 241(a)).

This generic clearance is necessary to enable CFSAN to understand stakeholders' perceptions, attitudes, motivations, and behaviors. Understanding these perceptions, attitudes, motivations, and behaviors plays an important role in improving FDA's communications which impact these various stakeholders and assists in the development of quantitative study proposals to complement other important research efforts in the Agency. To ensure that communications activities have the highest effect, we will conduct research and studies relating to the control and prevention of disease and the safety and health of the public. We intend to collect qualitative information that will be used to inform the regulatory science knowledge base, as well as to explore areas of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the agency. The information gathered may also be used to help develop communications and educational messages related to public health.

We therefore request extension of approval for the generic collection as 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<sup>1</sup> 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. In conducting studies relating to the

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<sup>1</sup> [Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies \(July 22, 2016\)](#).

control and prevention of diet-related disease, foodborne illness and other adverse events related to food and cosmetic products, dietary supplements, and animal food and feed, FDA will need to employ qualitative research to assess knowledge and perceptions about topics in the abovementioned areas with specific target audiences.

Therefore, FDA will collect, analyze, and interpret information gathered through this generic clearance in order to: (1) gain an in-depth understanding of a pertinent research area and topic; (2) better understand characteristics of the target audience—its perceptions, knowledge, attitudes, beliefs, and behaviors—and use these in the development of appropriate survey/research questions, study stimuli, and materials directed to consumers and industry; (3) more efficiently and effectively design survey/research questions and study stimuli; and (4) more efficiently and effectively design experimental studies; and

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 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<sup>2</sup> and is not retained;
- Information gathered will not be used for substantially informing influential policy decisions;<sup>3</sup> and
- Information gathered will yield qualitative information; 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 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 interview or moderator guide, screening questionnaire).

The types of collections that this generic clearance covers include, but are not limited to:

- Individual in-depth interviews (IDIs)
- Focus Groups
- Small Group Discussions
- Observations

### 3. Use of Improved Information Technology and Burden Reduction

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<sup>2</sup> For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All privacy act requirements will be met.

<sup>3</sup> 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.”

Consideration will be given to collecting information electronically or using online collaboration tools to reduce burden. Therefore, approximately 85 percent of these information collections will be completed electronically. To facilitate interpretation, discussions are recorded and videotaped (when appropriate) so that both a visual record and written transcript of the discussion are available for review.

#### 4. Efforts to Identify Duplication and Use of Similar Information

As each new research study is developed, FDA will review existing literature and databases, including pretesting reports on existing messages and materials. 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 food and cosmetic products, dietary supplements, and animal food and feed with the general public.

However, because communications to consumers, surveys, and studies about food and cosmetic products, dietary supplements, and animal food and feed will be diverse and vary by target audience, new data collection instruments generally will be prepared for each qualitative study.

Therefore, data collected by FDA is unique. Coordination with other agencies ensures that duplicative data is not being gathered. Further, with each new qualitative data collection, FDA will ensure that no similar data are gathered or maintained by FDA or are available from other sources known to FDA. We are unaware of duplicative information collection.

#### 5. 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.

#### 6. Consequences of Collecting the Information Less Frequently

Qualitative information is often used as a first step to explore concepts of interest and assist in the development of quantitative study proposals. The collection of timely data will be important to the development and conduct of ongoing and future research efforts at the Agency. Without feedback about consumer knowledge and perceptions, FDA will not have timely information to adjust its survey/research questions, study stimuli and draft communication messages.

Qualitative research methods may also be used to help develop materials directed at consumers and industry. FDA is using a variety of messages and materials to inform and educate the public about food and cosmetic products, dietary supplements, and animal food and feed.

Communicating effectively on these topics involves conveying complex concepts, and without detailed data from qualitative testing, FDA cannot fully ensure that these messages and materials directed at consumers are serving their intended purpose. Thus, FDA could spend a large amount of money on communications, surveys, or other studies 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

There are no special circumstances for this collection of information. The information collected will be voluntary and will not be used for statistical purposes.

#### 8. 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 on the proposed collection of information in the Federal Register of April 10, 2023 (88 FR 21193). One comment was received but was not responsive to the four collection of information topics solicited and therefore will not be discussed.

#### 9. Explanation of Any Payment or Gift to Respondents

It is standard practice in commercial market research to offer recruited participants some form of remuneration for the time they spend engaged in a personal interview activity. Instances for offering a small incentive will be determined on a case-by-case basis (depending on the information collection design). Incentive amounts will vary by type of qualitative method, the market rate of the geographic location for in-person research, and the difficulty of the recruit. Incentive amounts for information collections with general consumers submitted under this generic will typically not exceed \$75, though more may be requested for difficult-to-recruit populations. Details and justification on each incentive request will be included in each individual submission.

#### 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 ICR will collect personally identifiable information (PII). The PII collected typically consists of name and contact information. PII is collected on behalf of the FDA by a contractor or vendor who conducts surveys. Only the contractor conducting the research will have access to PII. 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 for scheduling and remuneration purposes. All 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 survey has been completed. In keeping with IRB/Human Subjects Research protocols, the FDA 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).

FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor does not use name or any other personal identifier to retrieve records from the information collected.

#### 11. Justification for Sensitive Questions

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

## 12. Estimates of Annualized Burden Hours and Cost

A variety of instruments and platforms will be used to collect information from participants. The annual participant burden hours requested (7,394) are based on the number of collections we expect to conduct over the requested time frame for this clearance.

### 12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Type of Interview	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Individual In-Depth Interview Screening	4,800	1	4,800	.08 (5 minutes)	384
Individual In-Depth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening	10,800	1	10,800	.08 (5 minutes)	864
Focus Groups/Small Group Discussion	3,600	1	3,600	1.5	5,400
Observation Screening	720	1	720	.08 (5 minutes)	58
Observations	144	1	144	2	288
<b>TOTAL</b>			20,464		7,394

### 12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. As of May 2022, the mean wage hourly compensation for this group is \$29.76<sup>4</sup>. The estimated annualized cost for the general public in this information collection for 7,394 hours of reporting time is \$220,045.44. The number of participants and length of response was determined based on 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.

Table 2.-Estimated Annual Reporting Cost Burden

Type of Interview	Total Burden Hours	Average Rate	Total Participant Cost
Individual In-Depth Interview Screening	384	\$29.76	\$ 11,427.84
Individual In-Depth Interviews	400	\$29.76	\$ 11,904.00
Focus Group/Small Group Participant Screening	864	\$29.76	\$ 25,712.64

Focus Groups/Small Group Discussion	5,400	\$29.76	\$160,704.00
Observation Screening	58	\$29.76	\$ 1,726.08
Observations	288	\$29.76	\$ 8,570.88
<b>TOTAL</b>			<b>\$220,045.44</b>

<sup>4</sup> U.S. Bureau of Labor Statistics, [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm), May 2022.

### 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

FDA incurs costs to conduct qualitative research, including potentially hiring a contractor to provide a facilitator/moderator, rent meeting space, travel to conduct the groups, and provide participants with minimum payment cost in the form of a token stipend.

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 may vary from \$20,000-\$250,000 depending on the size of the study. Therefore, in a given year, it is anticipated that approximately \$1 million 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 2023 is \$ 53.67 per hour, and doubling this to \$107.34 an hour to account for overhead, \$56,031.48 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is \$1,056,031.48 (which is equal to the total of contractor expenses (\$1 million) plus FDA government staff salary cost (\$56,031.48)).

### 15. Explanation for Program Changes or Adjustments

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

### 16. Plans for Tabulation and Publication and Project Time Schedule

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be statistically generalized to the overall population. Findings will be used to inform experimental research, public education, or communication activities.

Although FDA does not intend to publish its findings, FDA may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). FDA will disseminate the findings when appropriate, strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public," and will include specific discussion of the limitation of the qualitative results discussed above.

It is not appropriate to treat focus group data as quantifiable. FDA will disseminate focus group findings only when appropriate and will include specific discussion of the limitations of focus group results with regard to being non-quantitative. Information quality encompasses (1) utility, the usefulness of the information to its intended users, including the public; (2) objectivity, whether information is being presented in an accurate, clear, complete, and unbiased manner; and (3) integrity, the information is protected from unauthorized access or revision. FDA uses a number of mechanisms to ensure the quality of the information we disseminate. FDA reviews the quality of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance, and dissemination.

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

We are not requesting an exemption to this requirement. The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities comply with the requirements in 5 CFR 1320.9 and involve no exceptions to the Certification for Paperwork Reduction Act Submissions.