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-NEW

SUPPORTING STATEMENT

**Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act, or the Act) (21 U.S.C. 355), which provides that FDA may take appropriate action to protect the public health when necessary. The act also authorizes FDA to conduct educational and public information programs (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, FDA’s Center for Food Safety and Applied Nutrition 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)).

Accordingly, FDA is requesting approval of this new generic for collecting information using qualitative methods (i.e., individual in-depth interviews (IDIs), focus groups, small group discussions, and observations) for studies about food and cosmetic products, dietary supplements, and animal food and feed. Qualitative studies play an important role in exploring areas of research and gathering information because the studies allow for an in-depth understanding of individuals’ attitudes, beliefs, motivations, and feelings. This information 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. This information may also be used to help develop communications and educational messages related to public health.

FDA will submit individual qualitative collections under this generic clearance to the Office of Management and Budget (OMB). Individual qualitative collections will also undergo review by FDA’s Institutional Review Board (FDA IRB), 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.

We therefore request OMB approval of the generic collection as discussed in this supporting statement.

1. Purpose and Use of the Information Collection

In conducting studies relating to the 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. The information collected will serve two major purposes. First, it will provide critical knowledge about target audiences. FDA must first understand people’s knowledge, attitudes, beliefs, perceptions, and behaviors prior to developing survey/research questions, stimuli for experimental studies, and draft communication messages directed at consumers and industry. Second, the data will allow FDA to explore consumer understanding of potential survey/research topics and draft messages. These qualitative data collection methods will allow FDA to generate exploratory data on a given research topic or area of research, and to inform survey/research questions and study stimuli while they are still in the developmental stage.

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[[1]](#footnote-1) and is not retained;
* Information gathered will not be used for substantially informing influential policy decisions;[[2]](#footnote-2) 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.

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 interview or moderator guide, screening questionnaire).

1. Use of Improved Information Technology and Burden Reduction

Consideration will be given to collecting information electronically or using online collaboration tools to reduce burden. However, the applicability of such tools to in-person interviews and/or discussions is at present relatively unlikely, since the quality and level of detail in qualitative data collection would be difficult to obtain via virtual data collection methods. Therefore, due to the nature of qualitative research, approximately 5 percent of these information collections will be completed electronically.

1. 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.

1. 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.

1. 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.

1. 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.

1. 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 February 10, 2020 (85 FR 7564). Although five comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

1. 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.

1. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII) or information of a personal nature. PII collected is contact information. This information collection is a survey 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. FDA is authorized to take appropriate action to protect the public health when necessary and is authorized to conduct educational and public information programs. To ensure that regulatory actions and communications activities have the highest potential to be received and understood, FDA is requesting approval of this new generic for collecting information using qualitative methods (i.e., individual in-depth interviews (IDIs), focus groups, small group discussions, and observations) for studies about food and cosmetic products, dietary supplements, and animal food and feed.

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

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

Information provided by participants will be kept secure to the extent allowable by law. Information about privacy requirements will be communicated to participants by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups, telephone 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.

Only the contractor conducting the research will have access to personally identifiable information (PII). PII will be limited to information that may be required for recruiting the participant. PII will not be linked to information or interview data provided by the contractor to FDA. All PII will be destroyed at the completion of the study. Neither FDA employees nor any Federal employee of any other agency will have access to a participant’s PII.

All electronic and hard copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers and hard copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy, all data will be presented in aggregate, with no ability to identify individuals.

Interviews are typically considered exempt from the “Regulations for the Protection of Human Subjects” in accordance with 45 CFR 46.101(b)(3). FDA researchers will obtain either an exemption or a full approval for all research from FDA’s Institutional Review Board (IRB).

1. 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.

1. 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, by Anticipated Data Collection Methods**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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 |
| TOTAL  | 20,464 |  |  |  | 7,394 |

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The average hourly compensation for this group is $24.98.4 The estimated annualized cost for the general public in this information collection for 7,394 hours of reporting time is $184,702.12. 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.

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Interview | **Total Burden Hours** | **Average Rate**  | **Total Participant Cost** |
| Individual In-Depth Interview Screening | 384 | $24.98 | $ 9,592.32 |
| Individual In-Depth Interviews | 400 | $24.98 | $ 9,992.00 |
| Focus Group/Small Group Participant Screening | 864 | $24.98 | $ 21,582.72 |
|  Focus Groups/Small Group Discussion | 5,400 | $24.98 | $134,892.00 |
| Observation Screening | 58 | $24.98 | $ 1,448.84 |
| Observations | 288 | $24.98 | $ 7,194.24 |
| TOTAL  | $184,702.12 |

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

1. 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.

1. 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 2020 is $ 47.52 per hour, and doubling this to $95.04 an hour to account for overhead, $49.610.88 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is $1,049,610.88. (which is equal to the total of contractor expenses ($1 million) plus FDA government staff salary cost ($49,610.88)).

1. Explanation for Program Changes or Adjustments

This is a new collection of information. The estimated burden hours for focus groups for this collection of information have been increased from the burden published in the 60-Day Federal Register Notice of February 10, 2020 (85 FR 7564) to the burden published in the 30-Day Federal Register Notice (and captured in Item 12 of this supporting statement.) This adjustment in burden hours for focus groups reflects the increased need for this type of data collection across the abovementioned topic areas.

1. 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.

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.

1. 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.

1. 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.

1. 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. [↑](#footnote-ref-1)
2. 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.” [↑](#footnote-ref-2)