

United States Food and Drug Administration

FDA Focus Groups and Interviews

OMB Control No. 0910-0497 -- EXTENSION

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 or we), 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)).

We are requesting approval of this extension for collecting information through the use of focus groups and in-depth interviews for research involving all products regulated by FDA.

2. Purpose and Use of the Information Collection

This information will be used as a first step to explore concepts 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 communication messages and campaigns.

Focus groups play an important role in gathering information because they allow for a better understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies and encourages interaction between participants. Individual interviews allow for a more comprehensive, in-depth information exchange where more insights are likely to be collected. Both focus groups and in-depth individual interviews serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research, tool have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers' attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA understands that these methods do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use findings to test and refine their ideas but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

Upon extension of OMB approval, and as directed by OMB's terms of clearance of approval of this information collection, FDA will provide summaries of focus groups conducted over the last three years.

Respondents to this collection of information will include members of the general public, health care professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction. Inclusion and exclusion criteria will vary depending on the research topic.

3. Use of Improved Information Technology and Burden Reduction

This research will utilize directed group discussions and interviews that enable skilled observers to infer the underlying views and assumptions of the group members that are expressed in the discussion. To facilitate interpretation, discussions are audio- and video-recorded (when appropriate) so that both a visual record and written transcript of the discussion are available for review. FDA's focus groups and interviews will be held virtually or in-person at locations that participants travel to by car or short-range public transportation. When a specialized population of participants is necessary, such as physicians with expertise in a particular specialty, focus groups may be held at scientific or academic meetings. Some geographic diversity may be built in where such diversity is deemed appropriate by conducting focus groups in different regions across the United States.

4. Efforts to Identify Duplication and Use of Similar Information

It is not expected that any of the information gathered during these focus group studies or interviews is duplicative or is already in the possession of the Federal government. The proposed research will address FDA's needs and significantly improve our ability to explore and refine ideas. For each information collection proposed under this clearance, FDA will ensure that the information proposed for collection is not available elsewhere.

5. Impact on Small Businesses or Other Small Entities

FDA does not intend for these focus groups or interviews to be held with small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

Usually, a set or series of focus groups or interviews is collected only once to provide information or explore a particular topic of interest. Because this research is considered a first step to explore concepts of interest and develop quantitative research proposals, failing to collect the information will cause delays in the development of programmatic concepts and impede the development of quantitative research, which will in turn inhibit substantive policy formation. In addition, with respect to developing communications, in the absence of information collected through qualitative formative testing, the messages developed are much less likely to be effective and hence run the risk of being an inefficient use of government resources.

If this information is not collected, a vital link in gathering information by FDA to develop policy and programmatic proposals will be missed causing further delays in the development of such.

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

There are no special circumstances for this collection of information.

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

FDA will use routine contacts with customers, its own review of subject materials and other qualitative information collection activities to identify areas of interest and concern to customers. FDA will use in-house social science staff and outside contractors to develop focus group plans. FDA will provide OMB with all materials used in each individual generic submission for review and approval prior to collection.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in FEDERAL REGISTER of April 11, 2023 (88 FR 21680) to which we received three comments. Two were in support of the information collection and one did not address the elements of the PRA.

9. Explanation of Any Payment or Gift to Respondents

Incentives offered will reimburse respondents for the use of personal computers, quiet space, etc., for virtual focus groups and interviews as well as their time to travel locally, including parking cost, if any, for in-person appearances. Incentives will be decided on a case-by-case basis and will be stated in each individual generic submission.

Consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment due to lower response and enrollment levels, and/or the need to schedule additional groups to achieve the overall number of participants,
- Skewed participant demographics, with increased representation of participants with lower incomes and lower education levels,
- Increased likelihood of “no-shows” (which may result in methodologically unsound focus groups with small numbers of participants), and
- Increased probability that a focus group or interview may need to be cancelled or postponed because of insufficient numbers recruited by the scheduled date of the focus group, which not only incurs additional costs but also puts additional burden on the recruited participants who must reschedule their participation in the focus group.

The proposed incentive amount will help ensure that respondents honor their commitment of participating in the research. FDA will ensure that the proposed incentive is comparable to the level of incentive for the target audiences in similar government-funded activities.

For hard-to-reach respondents where a higher incentive might be offered, we will provide a justification in each individual generic submission.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identified information (PII) or information of a personal nature. PII collected is contact information. This ICR is collecting information from our customers which will help FDA understand consumers attitudes and emotions in response to topics and concepts, and as a result will help develop communication messages and campaigns. 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.

The information collected from respondents will be secured by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. FDA will never be given respondent surnames and will keep all recordings under lock and key. Contractor reports do not associate personal identifiers with any statements excerpted for illustrative purposes. Information will be kept secure to the furthest extent of the law.

11. Justification for Sensitive Questions

For the vast majority of this research, no questions will be asked that are of a personal or sensitive nature. Some products regulated by FDA are for conditions that are considered personal and potentially embarrassing. Therefore, there may be instances in which a particular topic of interest touches upon issues that could be considered sensitive. In these cases, extra care will be taken to ensure that any questions are absolutely necessary to the purpose of the information collection, are asked in a sensitive and respectful way, and that participants' right to refuse response is protected.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

All FDA centers may utilize this generic to gain feedback on a variety of topics involving all FDA-regulated products.

The number of groups will vary potentially representing different geographic and educational strata.

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
12,000	1	12,000	1.75	21,000

12b. Annualized Cost Burden Estimate

We project that the general public will complete the majority of data collections with less research focused on physicians and medical specialists. The average salary for this group is indicated in the table below. The total estimated hours multiplied by the average hourly wage rate as indicated by the U.S. Bureau of Labor Statistics is multiplied to arrive at the total respondent cost.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Focus group participant (general public)	12,000	\$33.09	\$397,080
Focus group participant (physicians, medical specialists)	9,000	\$133.14	\$1,198,260
Total			\$1,595,340

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 set up the focus groups, including hiring a contractor to provide a facilitator/moderator, rent meeting space, travel to conduct the groups, and provide respondents with payment of a de minimis cost in the form of a token stipend. We estimate the cost to federal government for this research to be \$350,000 annually.

15. Explanation for Program Changes or Adjustments

The estimated burden for the information collection reflects an overall increase of 5,600 hours and a corresponding increase of 3,200 responses. We increased these numbers based on the consolidation of ICR 0910-0677, "Focus Groups About Drug Products as Used by the Food and Drug Administration."

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results for this information collection. 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

FDA is requesting no exemption from display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.