United States Food and Drug Administration

Focus Groups as Used by the Food and Drug Administration (All FDA-regulated Products)

OMB Control No. 0910-0497

SUPPORTING STATEMENT

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) provides that FDA may take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Further, the act also authorizes FDA to conduct educational and public information programs (21 U.S.C. Section 393(d)(2)(D)).

The Food and Drug Administration (FDA) is requesting approval of this reinstatement for collecting information through the use of focus groups for studies involving all products regulated by FDA. 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 an in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings. Focus group research serves the narrowly defined need for direct and informal public opinion on a specific topic.

2. Purpose and Use of the Information Collection

Focus groups, used as a qualitative research tool, have three major purposes:

- To obtain consumer information 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.

Focus groups 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 focus groups 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 renewal 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

Focus group studies are directed group discussions 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 recorded and videotaped (when appropriate) so that both a visual record and written transcript of the discussion are available for review. Focus groups are generally held in 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 48 contiguous United States. Sometimes, however, when there is a particular need for rapidly gathering information from people who are located across the United States, focus groups may be held by telephone and may use Web technology to decrease burden and increase efficiency. FDA estimates that approximately 75% of the respondents will use electronic means to fulfill the agency's requirement or request.

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 is duplicative or is already in the possession of the Federal government. The proposed focus groups will address FDA's needs and significantly improve our ability to explore and refine ideas. For each study 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 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 is collected only once to provide information or explore a particular topic of interest. Because focus groups are 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, review of subject materials and other qualitative information collection activities to identify areas of interest and concern to customers. FDA will use in-house statistical staff and outside contractors to develop focus group plans. According to OMB guidelines for generic clearances for focus groups, FDA will establish an independent review process to assure the development and implementation of high quality focus groups by FDA. FDA will provide OMB a copy of the moderator guide for inclusion in the public docket.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in FEDERAL REGISTER of January 8, 2020 (85 FR 916). FDA received three comments. FDA thanks the commenters for their comments and provides our responses below. The first and second comments strongly support the proposed information collection related to focus groups used by the FDA. The third comment was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

It is standard practice to reimburse focus group respondents for their time and local travel and parking. Incentives will be decided on a case-by-case basis, and will be stated in each individual generic submission under this collection of information.

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 focus groups, 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

Each FDA center will utilize the focus group generic approval, as appropriate, on a variety of subjects, e.g. direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication, patient labeling, tampons, on-line sales of medical products, latex gloves, food safety, nutrition, dietary supplements, tobacco products, cosmetics, consumer education, animal nutrition, supplements, labeling of animal Rx.

Each study will include a variable number of groups, potentially representing different geographic and educational strata. Each focus group includes on average 9 participants and involves an average of 1.75 hours. The estimated total number of respondents is 8,800. Therefore, the total annual estimated burden imposed by this collection of information is approximately 15,400 hours.

Table 1.--Estimated Annual Reporting Burden[1]

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
8,800	1	8,800	1 hour and 45 minutes (1.75 hours)	15,400

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

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The average salary for this group is $16.26. The estimated annualized annual cost for the general public in this information collection for 10,010 hours is $162,762.60. Other labor groups include primary care physicians and medical specialists, whose average salary, respectively, is estimated as $124.63 and $129.93 (average used for total respondent cost estimate $127.28). The estimated annualized cost for physicians and medical specialists for 5,390 hours is $686,039.20. The estimated annualized cost for 15,400 burden hours is $806,059.10.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Focus group participant (general public)	10,010	$16.26	$162,762.60
Focus group participant (physicians, medical specialists)	5,390	$127.28	$686,039.20
Total			$848,801.80

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

Respondents will have no additional burden beyond the hours and cost burden shown in item A12b. Respondents will not need capital equipment, on-going recordkeeping operations, or services to complete the information collection. Therefore, there is no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The Agency 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. For these expenses, FDA spends approximately $240,000 annually.

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

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, strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public," 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.