Food and Drug Administration (FDA):
Focus Groups About Drug Products
OMB Control Number 0910-0677
Supporting Statement
Part A

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), the Commissioner of Food and Drugs is authorized to conduct educational and public information programs. To support these efforts, the Food and Drug Administration (FDA or we) is requesting approval for information collection through the use of focus groups for studies involving drug products that are regulated by the agency. The information collection will employ statistical methods, as described in our Supporting Statement Part B, 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

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, we will establish an independent review process to assure the development and implementation of high quality focus groups. Specifically we hope to utilize focus groups: to obtain information useful for developing variables and measures for quantitative studies; to better understand people's attitudes and emotions in response to topics and concepts; and to further explore findings obtained from quantitative studies.

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.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or other Small Entities

Respondents to the information collection are private individuals.

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.

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

There are no special circumstances for the collection of information.

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 in the Federal Register on November 7, 2016 (81 FR 78161). We received no comments that pertained to the information collection analysis.

9. Explanation of any Payment or Gift to Respondents

It is standard practice in commercial market research to offer recruited respondents some form of remuneration for the time they spend engaged in the focus group. As has been approved by OMB in the past, focus group participants may be offered an incentive (usually $50 to $75, consistent with general Federal government practice). Incentives for Web-based or telephone focus groups will generally be offered at a lower rate. Incentives for difficult-to-recruit populations may be offered at a higher rate such as $150 (or potentially more) for certain medical specialists. FDA will provide a rationale in the justification memo for any studies that propose to offer non-standard rates.

Circumstances, however, do not always require that remuneration be given; many audiences including the public, patients, survivors, and some health professionals often participate gratis because of their interest or involvement in the topic, or as a professional courtesy.

10. Assurance of Confidentiality Provided to Respondents

While anonymity of respondents generally cannot be assured unless there is a statutory requirement associated with the information collection, 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.

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 drug 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, 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

FDA staff were asked for the number of studies and size of the focus groups about drug products that they plan to conduct next year. The following burden estimates are based on FDA's projected focus group usage for the next year.

12a. Estimated Annual Reporting Burden

FDA's Center for Drug Evaluation and Research (CDER), the Office of the Commissioner, and any other agency components conducting focus groups about regulated drug products will utilize the focus group generic approval, as appropriate, on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician and other healthcare professional prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter drug labeling, emerging risk communications, patient labeling, on-line sales of medical products, and consumer and professional education.

FDA plans to conduct approximately 20 focus group studies using approximately 160 focus groups on a variety of topics related to regulated drug products. 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 lasts an average of 1.75 hours. The

estimated total number of respondents is 1,440. Therefore, the total annual estimated burden imposed by this collection of information is approximately 2,520 hours.

Table 1 – Estimated Annual Reporting Burden[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total Hours
Focus Group Study	1,440	1	1,440	1.75	2,520

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

12b. Estimated Annual Cost Burden

There are no annualized costs to respondents for the burden hours for this collections of information.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no capital or operating and maintenance costs associated with the 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 $200,000 annually.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments to this information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Although the agency has no plans to publish its findings, we may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). FDA will disseminate focus group findings only when appropriate, strictly following our "*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.

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.