FOCUS GROUPS ABOUT DRUG PRODUCTS,
AS USED BY THE FOOD AND DRUG ADMINISTRATION
OMB Control No. XXXX
SUPPORTING STATEMENT

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 for collecting information through the use of focus groups for studies involving drug products that are 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

If this information is not collected, a vital link in the research process will be lost, causing delays in the development of programmatic concepts and quantitative research proposals.

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

- 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.

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 to larger populations. As such, they cannot be used to drive the development of policies, programs, and services. FDA policy makers and educators will use focus groups findings to explore and refine their ideas, but will then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

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

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.

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

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) on 3/22/2010 FDA published a 60-day Federal Register notice (75 FR 13548).

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.

12A. Estimates of Annualized Burden Hours and Costs

Staff from FDA's Center for Drug Evaluation and Research (CDER) and staff within the Office of the Commissioner 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.

CDER, the Office of the Commissioner, and any other Centers or Offices 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 studies annually 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 involves 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.

12B. There are no annualized cost to respondents for the hour burdens for collections of information.

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	No. of Responses per Respondent	Total Annual Responses (hours)	Average Burden per Response (hours)	Total burden Hours
1,440	1	1,440	1.75	2,520

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

Respondents will have no additional burden beyond the hours burden shown in item A12. Respondents will not need capital equipment, on-going recordkeeping operations, or services to complete the information collection. As each information collection will be a one-time occasion, record keeping is not applicable.

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

This is a new collection.

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.

Although the Agency does not intend to publish its findings, the Agency 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 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

Not applicable.