FOCUS GROUPS AS USED BY THE FOOD AND DRUG ADMINISTRATION
OMB No. 0910-0497
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

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.

The Food and Drug Administration (FDA) is requesting approval for collecting information through the use of focus groups. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. It serves the narrowly defined need for direct and informal opinion on a specific topic.

2. How, By Whom, Purpose of Collection

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.

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.

As directed by OMB's terms of clearance of approval of this information collection, attached are summaries (Attachment A) provided by the Centers on focus groups they have conducted over the past 18 months.

3. Consideration Given to Information Technology

Focus group studies are directed group discussions that enable skilled observers to infer the underlying views and assumptions of the group that are expressed in the discussion. To

facilitate interpretation, discussions are recorded and videotaped so that both a visual record and written transcript of the discussion are available for review.

4. Duplication or 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 the needs of the Agency and significantly improve our ability to test and redefine ideas.

5. Minimize Burden to Small Entities

   Not Applicable

6. Consequences of Not Conducting Collection

   Usually FDA will collect data only once to provide information to gauge public opinion. Without these data collections, existing disagreements within the stakeholder community about how to proceed in a particular matter will be much harder to resolve. Without additional information of the kind that would be provided by the study, large segments of the stakeholder community will likely be unsatisfied with whatever option is adopted. Only by feeding information about the likely consumer impacts of different options back into the policy, program, or service allocation dialogue, will it be possible to bridge the gaps between stakeholders and arrive at a mutually acceptable policy, program, or service allocation decisions. Ultimately, the speed and level of marketplace adoption of policies, program, or service allocations depend on this information.

7. Information Collection Circumstances

   There are no special circumstances for the collection of information.

8. Consultations with Persons Outside FDA

   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 in developing 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 survey instrument for inclusion in the public docket.

   In accordance with 5 CFR 1320.8(d) on March 27, 2007, FDA published a 60-day Federal Register notice (72 FR 14279) to which FDA received no comment.

9. Payment or Gift

   It is standard practice to reimburse focus group respondents for their time. Incentives will be decided on a case-by-case basis.

10. Assurance of Confidentiality

The confidentiality of respondents will be assured 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.

11. Privacy

No questions will be asked that are of a personal or sensitive nature.

12. Burden of Information Collection

Each FDA center was asked for the number of studies and size of the focus groups that they plan to conduct next year. The following burden estimates are based on FDA's projected focus group usage for the next year.

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, FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves, food safety, nutrition, dietary supplements, and consumer education, animal nutrition, supplements, labeling of animal Rx.

FDA plans to conduct approximately 28 studies including 9 participants on a variety of subjects. The estimated total number of respondents is 2,574. Therefore, the total annual estimated burden imposed by this collection of information is approximately 4,252 hours.

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	No. of Responses per Respondent	Total Annual Responses (hours)	Average Burden per Response (hours)	Total burden Hours
2574	1	2574	1.65	4252

13. Cost to Respondents

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.

14. Costs to Federal Government

The Agency incurs costs to set up the focus groups including hiring the contractor (facilitator or moderator), renting meeting space, travel and subsistence and the payment of a de minimis cost in the form of a token stipend. For these expenses, FDA spends approximately $160,000 annually.

15. Reason for Change

No change since the last clearance.

16. Statistical Reporting

There are no tabulated results for this information collection.

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. Display of OMB Approval Date

FDA is requesting no exemption.

18. Exceptions to “Certification for Paperwork Reduction Act Submissions”

N/A.