

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

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting approval for the information collection requirements 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.

This information will be used to develop programmatic proposals that are aligned with the respondents' input. A focus group supplements other forms of public involvement. It serves the narrowly defined need for direct and informal opinion on a specific topic.

2. How, By Whom, Purpose of Collection

Every center in FDA will likely make use of focus groups for gauging public opinion. 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 November 25, 2005, FDA published a 60-day Federal Register notice (70 FR 71165) to which FDA received one comment. However, this comment was not related to the information collection.

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.

To arrive at each Center's estimated burden we multiplied the No. of Focus Groups per Study by the No. of Participants per Group. (Example, CBER:  $5 \times 9 = 45$ ). We multiplied that total by the Hours of Duration for Each Group to arrive at the total burden hours. (Example, CBER:  $45 \times 1.58 = 71.1$ )

The total annual estimated burden imposed by this collection of information is approximately 4,252 hours annually.

### ESTIMATED ANNUAL REPORTING BURDEN

FDA Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication)	10	200	9	1.58	2,844
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves)	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, and consumer education)	8	40	9	1.58	569

Center for Veterinary Medicine	Varies (e.g., animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468
Total		28	286	9	1.78	4,252

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

The increase in estimated total burden hours is attributed to an increase in CDER's projected use of focus groups.

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"

These activities will comply with the requirements in 5 CFR 1320.9.

**B. STATISTICAL METHODS**

There are no plans to publish this information for statistical use.

## Summaries of Focus Groups Conducted by the Food and Drug Administration

FDA Center	Title of Focus Group	Participants	Use of Information
CDER	Physicians on Factors Influencing Their Prescribing Habits	Group 1: General practitioners with more than 3 years experience Group 2: Internists with between 3 and 15 years experience Group 3: Internists with more than 15 years experience	To understand the role of different promotional tactics (e.g., detailing, professional advertising, direct-to-consumer advertising, the Internet) on the decisions of physicians to prescribe certain drugs.
CFSAN	Allergen Labeling Focus Groups	8 groups, 2 moderators	The Consumer Studies' Final Report was given to the CFSAN team that is currently developing a proposed rule on food allergen labeling that will address the eight most common food allergens. The Final Report has not been distributed to the public.
CFSAN	Graphic Devices to Signal Level of Scientific Evidence for Health Claims	8 groups, 2 moderators	The Consumer Studies' Final Report was used internally by Consumer Studies to help develop the experimental conditions for the qualified health claims experimental study. The Final Report has not been distributed to the public.
CFSAN	Food and Restaurant Labeling and Weight Management	8 groups, 2 moderators	Select findings from the Consumer Studies' Final Report were used in deliberations by the Commissioner's Obesity Work Group (OWG) and included in their report. The full OWG report was made available to the public and is currently on the FDA website. The Consumer Studies' Final Report has not been distributed to the public.
CFSAN	Methylmercury Advisory Focus Groups	16 groups, 2 moderators	The key findings were used by the interagency (FDA and EPA) workgroup and the Food Advisory Committee (FAC) to revise the content of the methylmercury advisory. The findings have not been distributed to the public. Representatives from industry and consumer advocates attended the focus groups and reported information to their respective stakeholders.
CDRH	Consumer Reaction to Labeling Messages About Condoms	36 (4 groups, 9 per group)	The purpose of the focus group study was to determine the perception, opinion, belief and attitude of the participants toward condom labeling messages.
OC	Consumer Perceptions of Food Derived From Animal Clones and Their Offspring	7 groups	Designing a communications plan.
OC	Perceptions of Nicotine	6 groups	

