

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0159]

DMB  
Display Date 8-29-02  
Publication Date 8-30-02  
Certifier R. LEDESMA

**Agency Information Collection Activities; Submission for OMB Review;  
Comment Request; Focus Groups as Used by the Food and Drug  
Administration**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1471.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Focus Groups as Used by the Food and Drug Administration—New Collection

FDA will collect and use information gathered through the focus group vehicle. 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.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

In the **Federal Register** of May 24, 2002 (67 FR 36613), the agency requested comments on the proposed collection of information. FDA received four comments, but they did not pertain to the information collection though one heartily supported the use of focus groups as an instrument to help FDA better understand how well respondents comprehend health issues.

FDA estimates the burden for completing the forms for this collection of information as follows:

The total annual estimated burden imposed by this collection of information is 2,884 hours annually.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Center	Subject	No. of Focus Groups per Study	No. of Focus Group Sessions Conducted Annually	Number 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	100	9	1.58	1,422

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

Center	Subject	No. of Focus Groups per Study	No. of Focus Group Sessions Conducted Annually	Number of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Devices and Radiological Health.	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves).	5	25	9	2.08	468
Center for Food Safety and Applied Nutrition.	Varies (e.g., food safety, nutrition, dietary supplements, and consumer education).	8	32	9	1.58	455
Center for Veterinary Medicine.	Varies (e.g., food safety, labeling, cosmetic safety and labeling).	5	25	9	2.08	468
Total		29	187		1.99	3,352

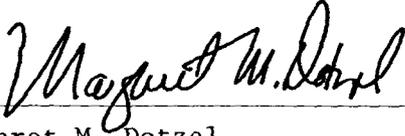
<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection.

Annually, FDA projects about 29 focus group studies using 187 focus groups lasting an average of 1.99 hours each. We have allowed burden for unplanned focus groups to be completed so as not to restrict the agency's

ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: 8-26-02

August 26, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

