

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0159]

DMB

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Certifier G. Presley

**Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on focus groups as used by FDA. These focus groups gauge public opinion, and policymakers can use focus group findings to test and refine their ideas so they can conduct further research whose findings can be used to adopt new policies and to allocate or redirect significant resources to support these policies.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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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: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Focus Groups as Used by the Food and Drug Administration

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such complements other important research findings to develop these proposals. Focus groups do provide an important role

in gathering information because they allow for a more indepth 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.

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 BURDEN¹

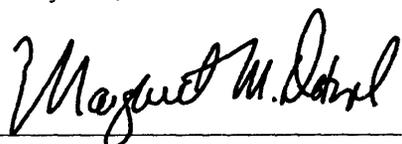
Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug 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	100	9	1.58	1,422
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, online 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		1.71	2,884

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Annually, FDA projects about 29 focus group studies using 187 focus groups lasting an average of 1.71 hours each. FDA has 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: 5-14-02

May 14, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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