

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0249]

DMB

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Agency Information Collection Activities; Submission for OMB Review; Comment Request; Consumer and Producer Surveys on Economic Issues

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

Consumer and Producer Surveys on Economic Issues

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)), FDA is authorized to conduct research relating to regulated articles and to collect information

relating to responsibilities of the agency. Executive Order 12866, the Regulatory Flexibility Act (RFA), and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) direct Federal agencies to conduct regulatory impact analysis, and to consider flexible regulatory approaches. In order to perform the mandatory analysis it is often necessary to survey: (1) Regulated producers to determine existing practices and the changes in those practices likely under various policy options, (2) both consumers and manufacturers to explore attitudes towards policy proposals, and (3) industry experts to solicit expert opinions. FDA is seeking OMB clearance to conduct future surveys to implement Executive Order 12866, RFA, and SBREFA. Participation in the surveys will be voluntary. This request covers regulated entities, such as food processors, dietary supplement manufacturers, health professionals or other experts, and consumers.

FDA will use the information gathered from these surveys to identify current business practices, expert opinion, and consumer or manufacturer attitudes towards existing or proposed policy. FDA projects approximately 2 to 6 surveys per year, with a sample of between 10 and 1,000 respondents each for mail and telephone surveys, and a sample of up to 3,000 respondents for cable or Internet surveys.

In the **Federal Register** of June 15, 2001 (66 FR 32625), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the upper bound burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Mail questionnaire	1,000	1	1,000	3	3,000
Phone survey	1,000	1	1,000	0.5	500
Internet or cable survey	3,000	1	3,000	1	3,000
Total					6,500

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

These estimates are based on the expected number of respondents necessary to obtain a statistically significant stratification of the average to large size industries—including small business entities covered by FDA regulations—and consumers of regulated products.

Dated: 8/24/01

August 24, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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