

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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[Docket No. 00N-1534]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Year 2000 Continuation of the National Surveys of Prescription Drug Information Provided to Patients**

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

**ACTION:** Notice.

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**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:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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.

## **Year 2000 Continuation of the National Surveys of Prescription Drug Information Provided to Patients**

FDA implements the provisions of the Federal Food, Drug, and Cosmetic Act (the act) designed to assure the adequate labeling of prescription (Rx) drugs. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug product is misbranded if its labeling is false or misleading in any particular, and under section 201(n) of the act (21 U.S.C. 321(n)), a drug's labeling is misleading if its labeling or advertising fails to reveal material facts. FDA also has the authority to collect this information under Title VI of Public Law 104-180 (Related Agencies and Food and Drug Administration) section 601 (Effective Medication Guides), which directs the development of "a mechanism to assess periodically \* \* \* the frequency with which the [oral and written prescription] information is provided to consumers."

To assure that Rx drugs are not misbranded, FDA has historically asserted that adequate labeling requires certain information be provided to patients. In 1982, when FDA revoked a planned initiative to require mandatory patient package inserts for all Rx drugs in favor of private sector initiatives, the agency indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis. In addition, FDA has been responsible for setting and tracking Healthy People 2000 goals and now for Healthy People 2010 goals for the receipt of medication information by patients.

Surveys of consumers about their receipt of Rx drug information were carried out in 1982, 1984, 1992, 1994, 1996, and 1998. This notice is in regard to conducting the survey in 2000.

The survey is conducted by telephone on a national random sample of adults who received a new prescription for themselves or a household member within the past 4 weeks. The interview assesses the extent to which oral and written information were received from the doctor, the pharmacist, and other sources. Survey respondents are also asked attitudinal questions, and demographic and other background characteristics are obtained. The survey enables FDA to determine the frequency with which such information is provided to consumers. Without this

information, the agency would be unable to assess the degree to which adequate patient information and counseling about Rx drugs is provided.

Respondents to this collection of information are adults (18 years or older) in the continental United States who have obtained a new (nonrefill) prescription at a pharmacy for themselves or a member of their household in the last 4 weeks. This survey may be seen online at <http://www.fda.gov/cder/ddmac/y2kttitle.htm>.

In the **Federal Register** of October 6, 2000 (65 FR 59849), FDA invited comments on the proposed information collection. No significant comments were received.

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

TABLE 1.—Estimated Annual Reporting Burden<sup>1</sup>: Screener

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2000 Total	9,643	1	9,643	.03	289 289

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

TABLE 2.—Annual Reporting Burden<sup>1</sup>: Survey

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2000 Total	1,000	1	1,000	.32	320 320

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

This total estimate of 609 total annual burden hours is based on the 1998 survey administration, in which 9,643 potential respondents were contacted to obtain 1,000 interviews.

Dated: December 27, 2000



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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