Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of ''Geriatric Use'' Subsection in the Labeling (OMB Control Number 0910–0370)—Extension

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the ''Precautions'' section of prescription drug labeling must include a subsection on the use of the drug in elderly or geriatric patients (aged 65 and over). The information collection burden imposed by this regulation consists of designing, testing, and submitting the geriatric use subsection of the labeling. The regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)—new drug applications	83	1.49	124	8	992
201.57(f)(10)—abbreviated new drug applications	117	3.96	464	2	928
Total					1,920

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

Dated: December 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–264 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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.

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 February 5, 2001.

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/y2ktitle.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[1]: SCREENER

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

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

TABLE 2.—ANNUAL REPORTING BURDEN[1]: SURVEY

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

[1]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.

[FR Doc. 01–265 Filed 1–4–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0472]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Petition for Administrative Stay of Action

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 February 5, 2001.

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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Petition for Administrative Stay of Action—21 CFR 10.35 (OMB Control Number 0910–0194)—Reinstatement)—Extension

The regulations in 21 CFR 10.35, issued under the authority of section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), set forth the format and procedures by which an interested person may file a petition for an administrative stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Such a petition must: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. The information provided in the petition is used by the agency to determine whether the requested stay should be granted.

In the **Federal Register** of September 25, 2000 (65 FR 57614), the agency requested comments on the proposed collections of information. No significant comments were received.

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