TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
314.70(f)	43	1	43	1	43
314.94(a)(12)	395	1	395	2	790
314.95	30	1	30	16	480
314.107(c)(4), (e)(2)(iv), (f)(2), and (f)(3)	30	1	30	1	30
Total					1,731

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

This estimate is based on FDA's experience over the last 3 years in receiving this information, and the familiarity by FDA reviewers with the amount of time it takes to prepare and submit the information to FDA.

Dated: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7474 Filed 3–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0488]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by April 22, 1998.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC, 20503, Attn: 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Year 1998 and 2000 Continuation of National Surveys of Prescription Drug Information Provided to Patients—(OMB Control Number 0910–0279—Reinstatement)

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 Pub. L. 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 in this area, the agency indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis. Surveys of consumers about their receipt of Rx drug information were carried out in 1982, 1984, 1992, 1994, and 1996. This notice is in regard to continuing the survey in years 1998 and 2000.

The survey is conducted by telephone on a national random sample of adults age 18 and over 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 was received from the doctor, the pharmacist, and other sources. Survey respondents are also asked attitudinal questions, and demographic and other background characteristics are also 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 assure that adequate Rx labeling and information is provided.

Respondents to this collection of information are adults (18 years or older), in the continental United States who have obtained one or more new (nonrefill) prescriptions at a pharmacy for themselves or a member of their household in the last 4 weeks.

In the **Federal Register** of December 11, 1997 (62 FR 65273), the agency invited comments on the collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN: SCREENER[1]

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1998	11,044	1	11,044	.03	331
1999	0	0	0	0	0
2000	11,044	1	11,044	.03	331
Annual average	7,363		7,363		221

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

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

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1998	1,000	1	1,000	.32	320
1999	0	0	0	0	0
2000	1,000	1	1,000	.32	320
Annual average	667		667		213

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

This estimate of 434 total annual burden hours is based on the 1996 survey administration, in which 11,044 potential respondents were contacted to obtain 1,000 interviews.

Dated: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7475 Filed 3–20–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0486]

Agency Information Collection Activities; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution; Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by April 22, 1998.

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: 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (21 CFR Part 207)—(OMB Control Number 0910–0045)

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207). The regulations require an initial listing of products and a twice-yearly update. In addition, all registered drug firms are required to re-register annually between January and July. The penalties for failure to register or drug list are potential seizure and injunctions, as well as criminal enforcement actions.

The following are the specific reporting requirements under part 207: (1) Section 207.20 requires that owners and operators of all drug establishments that engage in the manufacture, preparation, propagation, or processing of drugs must register and use Form FDA 2656 (Registration of Drug Establishment) and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors) to submit drug listing information or to request a Labeler Code, or both. (2) Section 207.21 requires that owners and operators must register an establishment within 5 days of beginning operations and shall complete Form FDA 2656e (Annual Registration of Drug Establishment) each year between January and July. Annual registration forms are mailed by FDA in each calendar year according to a schedule based on the establishment parent company's name and must be completed within 30 days of the receipt. (3) Section 207.22(a) requires that Form FDA 2656 must be submitted when an establishment registers the first time. An establishment whose drug registration is validated under § 207.35(a) is required to make subsequent annual registrations as described in § 207.21(a). (4) Section 207.22(b) requires that Form FDA 2657 must be submitted for the first listing of drugs and subsequent June and December updates. (5) Section 207.25 specifies the information required in the establishment registration and drug listing. (6) Section 207.25(c) specifies the information about the drug that is required to be submitted (name, active ingredients, dosage strength, NDC number, manufacturer or distributor, size, shape, color, code imprint). (7) Section 207.26 specifies the information required in the amendments to the establishment registration. (8) Section 207.30 specifies the information required for updating the drug listing. (9) Section 207.31 specifies additional drug listing information that may be needed beyond that required in §§ 207.25 and 207.30.

The information obtained from the establishment registration forms FDA 2656 and FDA 2656(e) is used by FDA and other government agencies to keep an accurate and current list of all human and animal drug manufacturers, repackers, relabelers, and other drug processors located in this country. This list is used by FDA for inspectional