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.

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

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

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1998	1,000	1	1,000	.323	20
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: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32460 Filed 12–10–97; 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: Proposed Collection; Comment Request

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing the registration of producers of drugs and listing of drugs in commercial distribution.

DATES: Submit written comments on the collection of information by February 9, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

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: 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 1320.39(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 listed below.

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.

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

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 the 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 purposes as required by the act. In addition, the data is used by the public and private sector as a listing of the names and locations of drug firms. The information obtained from the listing forms FDA–2657 and FDA–2658 is used, through assignment of the National Drug Code numbers, for third party reimbursement payment in Medicare and Medicaid as well as other health care insurance firms.

Respondents to this collection of information are all owners and operators that engage in the manufacture, preparation, propagation, compounding, or processing of drugs and that are not exempt under section 510(g) of the act or subpart D of 21 CFR 207.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Form FDA–2656 Registration of Drug Establishment	207.20 207.22 207.25 207.26	2,500	1	2,500	.5	1,250
Form FDA–2656(e) Annual Re-registration of Drug Establishments	207.21 207.25 207.26	9,000	1	9,000	.5	4,500
Form FDA–2657 Drug Product Listing Form	207.22 207.30 207.31	45,000	1	45,000	.5	22,500
Form FDA–2658 Registered Establishment's Report of Private Label Distribution	207.20 207.21 207.25 207.26	6,200	1	6,200	.5	3,100
	207.25(c)	1,500	12.04	18,066	.5	9,033
Total						40,383

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

These estimates are based on FDA's Center for Drug Evaluation and Research, Product Information Management Branch, and its data and information on drug listing and establishment registration of manufacturers, repackers, relabelers, and other drug processors.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32461 Filed 12–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0311]

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 following 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 this collection of information by January 12, 1998.

ADDRESSES: Submit written comments on this 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: 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 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.

CGMP and Related Regulations for Blood and Blood Components—(21 CFR Parts 606 and 640)—(OMB Control Number 0910–0116)—Reinstatement

Under the statutory requirements contained in the Public Health Service Act (42 U.S.C. 262), no blood, blood component, or derivative may move in interstate commerce unless: (1) It is propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license; (2) the product complies with regulatory standards designed to ensure safety, purity, and potency; and (3) it bears a label plainly marked with the product's proper name, its manufacturer, and expiration date.

The CGMP and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections. The recordkeeping requirements serve preventative and remedial purposes. The disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of any deviations that occur and that may require immediate corrective action.

Section 606.100(b) requires that written standard operating procedures (SOP's) be maintained for the collection, processing, compatibility testing, storage and distribution of blood and blood components used for transfusion and manufacturing purposes. Section 606.100(c) requires the review of all pertinent records to a lot or unit of blood prior to release of the lot or unit. Any unexplained discrepancy or failure of a lot or unit of final product to meet any of its specifications must be thoroughly investigated, and the investigation, including conclusions and followup, must be recorded. Section 606.110(a) requires a physician to certify in writing that the donor's health permits plateletpheresis or leukapheresis if a variance from additional regulatory standards for a specific product is used when obtaining the product from a specific donor for a specific recipient. Section 606.151(e) requires that records of expedited transfusions in life-threatening emergencies be maintained. So that all steps in the collection, processing, compatibility testing, storage and distribution, quality control, and transfusion reaction reports and complaints for each unit of blood and blood components can be clearly traced, § 606.160 requires that legible and indelible contemporaneous records of each significant step be made and maintained for no less than 5 years. Section 606.165 requires that distribution and receipt records be maintained to facilitate recalls, if necessary. Section 606.170(a) requires records to be maintained of any reports of complaints of adverse reactions as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and followup, must be prepared and maintained. Section 606.170(b) requires that fatal complications of blood collections and transfusions be reported to FDA as soon as possible and that a written report shall be submitted within 7 days. In addition to the CGMP's in part 606, there are regulations in part 640 that require additional standards for blood and blood components: §§ 640.3(a) and (f), 640.4(a), 640.25(b)(4) and (c)(1), 640.27(b), 640.31(b), 640.33(b), 640.51(b), 640.53(c), 640.56(b) and (d), 640.61, 640.63(b)(3), (e)(1) and (e)(3), 640.65(b)(2), 640.66, 640.71(b)(1), 640.72, 640.73, and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described below.

The recordkeeping requirements for §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOP's, are included in the estimate for § 606.100(b); the recordkeeping requirements for § 640.27(b), which addresses the maintenance of donor health records for plateletpheresis, is included in the estimate for § 606.110(a); and the recordkeeping requirements for §§ 640.3(a)(2), 640.3(f), 640.4(a)(2), 640.25(b)(4) and (c)(1), 640.31(b), 640.33(b), 640.51(b), 640.53(c), 640.56(b) and (d), 640.61, 640.63(b)(3), (e)(1), and (e)(3), 640.65(b)(2), 640.71(b)(1), 640.72, and 640.76(a) and (b), which address the maintenance of various records, are included in the estimate for § 606.160. The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

Respondents to this collection of information are registered blood establishments. There are an estimated 3,021 FDA registered blood collection facilities in the United States that annually collect an estimated 23,500,000 units of whole blood and source plasma. Of the 3,021 registered establishments, 1,799 establishments perform pheresis collections and 278 establishments perform transfusions.