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]

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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.

There are also an estimated 4,500 Health Care Financing Administration registered transfusion services. The recordkeeping chart reflects the estimate that 95 percent of the recordkeepers which collect 98 percent of the blood supply had developed SOP's as part of their normal business practice. Establishments may minimize burdens associated with the CGMP and related regulations by using model SOP's developed by blood organizations. These blood organizations represent almost all of the registered establishments.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(b)	42	1	42	8	336

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)	151	1	151	24	3,624
606.100(c)	151	3.6	550	3.6	550
606.110(a)	90	5	450	2.5	225
606.151(e)	239	12	2,868	1	239
606.160	151	3,112	470,000	1,556	234,956
606.165	151	3,112	470,000	258	38,958
606.170(a)	376	12	4,512	12	4,512

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

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32458 Filed 12–10–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0453]

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 January 12, 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: 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.

Human Tissue Intended for Transplantation (OMB Control Number 0910–0302)—Reinstatement

FDA issued final regulations in the **Federal Register** of July 29, 1997 (62 FR 40429) to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, and hepatitis C through the use of human tissue for transplantation. The final regulations closely parallel those contained in the interim rule on human tissue intended for transplantation. Both the interim and final rule provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet standards intended to ensure appropriate screening and testing of human tissue donors and ensure that records are kept documenting that the appropriate screening and testing have been completed.

There are approximately 60 tissue establishments with 300 employees that are members of the American Association of Tissue Banks. There are an additional 600 individual members of which 50 percent are performing a tissue banking activity. The Eye Bank Association of America's membership consists of 120 eye banks of which 110 are in the continental United States.

With the rare exceptions noted in the preamble of the rule, FDA believes that all respondents perform donor testing and screening for HIV and hepatitis and these regulations add no additional requirements. 21 CFR 1270.31(c) and (d) require written procedures for the designation and identification of quarantined tissue and to prevent the contamination or cross-contamination of tissue during processing. 21 CFR 1270.35(c) requires documentation of the distribution and receipt of human tissue, completing the accounting of tissue between determination of suitability, and the destruction or disposition of the tissue.

When the interim rule was issued in the **Federal Register** of December 14, 1993 (58 FR 65514), accredited members of the American Association of Tissue Banks and the Eye Bank Association of America were already in compliance with the regulations by adhering to the standards established by these organizations. The requirements in the