1. Annual progress reports;
2. Financial status report, no more than 90 days after the end of the budget period;
3. Final financial report and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–4 HIV/AIDS Confidentiality Provisions
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k) (2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2). The Catalog of Federal Domestic Assistance number is 93.941, HIV Demonstration, Research, Public and Professional Education Projects.

J. Where To Obtain Additional Information

This and other CDC [ATSDR] announcements can be found on the CDC home page Internet: http://www.cdc.gov. Click on ''Funding'', then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Annie H. Camacho, Grants Management Specialist, Centers for Disease Control and Prevention (CDC), Procurement and Grants Office, Room 3000, 2920 Brandywine Road, Mailstop E–15, Atlanta, GA 30341–4146, Telephone: (770) 488–2735, Email: atc4@cdc.gov.

For program technical assistance, contact: Leo Weakland, Deputy Coordinator, Global AIDS Activity (GAA), National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Mailstop E–07, Atlanta, GA 30333, Telephone number (404) 639–8016, Email address: lfw0@cdc.gov.

Dated: June 29, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control (CDC).

[FR Doc. 00–17011 Filed 7–5–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1353]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components

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 the information collection requirement relating to the regulation of FDA's current good manufacturing practice (CGMP) and related regulations for blood and blood components.

DATES: Submit written comments on the collection of information by September 5, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 1320.3(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.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components—Parts 606 and 640 (21 CFR Parts 606 and 640) (OMB Control Number 0910–0116)—Extension

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, 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) (21 CFR 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) (21 CFR 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 606.110(b) requires establishments to request prior Center for Biologics Evaluation and Research (CBER) approval for plasmapheresis of donors who do not meet donor requirements. The regulation in 21 CFR 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, 21 CFR 606.160 requires that legible and indelible contemporaneous records of each significant step be made and maintained for no less than 5 years. The regulations in 21 CFR 606.165 require that distribution and receipt records be maintained to facilitate recalls, if necessary. Section 606.170(a) (21 CFR 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 (21 CFR part 606), there are regulations in 21 CFR part 640 that require additional standards for blood and blood components as follows: Sections 640.2(f), 640.3(a), 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) (21 CFR 640.2(f), 640.3(a), 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.

Respondents to this collection of information are licensed and unlicensed blood establishments inspected by FDA, and other transfusion services inspected by the Health Care Financing Administration (HCFA) . Based on FDA's registration system, there are an estimated 3,032 registered blood establishments inspected by FDA of which 1,349 perform pheresis. Based on information provided by HCFA, there are an estimated 3,400 transfusion services inspected by HCFA. An estimated 27 million units of Whole Blood and blood components are collected annually. 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 customary and usual business practice. Establishments may minimize burdens associated with the CGMP and related regulations by using model SOP's developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments. The total annual responses in the reporting chart for fatality reporting are based on an annual average of fatality reports submitted to FDA. The annual frequency of recordkeeping and total annual records, and the estimated reporting and recordkeeping burden hours are based on information provided by industry, and FDA's experience. Under § 606.110(b), licensed establishments submit supplements to their biologics license applications to request prior CBER approval of plasmapheresis donors who do not meet donor requirements. The information collection requirements for § 606.110(b) are reported under OMB control number 0910–0315.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section[2]	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(b)	75	1	75	20	1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section[2]	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)	322[3]	1	322	24	7,728
606.100(c)	152[4]	26	4,000	1	4,000
606.110(a)	68[5]	5	340	0.5	170
606.151(e)	322[3]	12	3,864	0.083	321
606.160	322[3]	1,677	540,000	0.5	270,000

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section[2]	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.165	152[4]	3,553	540,000	0.083	44,820
606.170(a)	322[3]	12	3,864	1	3,864
Total					330,903

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

[2] The recordkeeping requirements in §§ 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 in § 640.27(b), which address the maintenance of donor health records for plateletpheresis, are included in the estimate for § 606.110(a); and the recordkeeping requirements in §§ 640.2(f), 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.

[3] 5 percent of HCFA and FDA-registered blood establishments (0.05 X (3,400 + 3,032))

[4] 5 percent of FDA-registered establishments (3,032)

[5] 5 percent of pheresis establishments (1,349)

Dated: June 27, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–16978 Filed 7–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1226]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Investigational Device Exemptions, Reports, and Records

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 August 7, 2000.

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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Investigational Device Exemptions, Reports, and Records—21 CFR Part 812 (OMB Control No. 0910–0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The FDA Modernization Act of 1997 added section 520(g)(6) to the act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement.

An IDE allows a device, which would otherwise be subject to provisions of the act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards.

To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, those that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, those that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements.

The regulation also includes provisions for treatment IDE's. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available.

Section 812.10 allows the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety.

Sections 812.20, 812.25, and 812.27, consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations. Section 812.20 lists the data requirements for the original IDE application, § 812.25 lists the contents of the investigational plan, and § 812.27 lists the data relating to previous investigations or testing. The information in this original IDE application is evaluated by the Center for Devices and Radiological Health to determine whether the proposed investigation will reasonably protect the public health and safety, and for FDA to make a determination to approve the IDE.

Once FDA approves an IDE application, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation which affects the scientific soundness of the study or the rights, safety, or welfare of