TABLE 5.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Total					36,040,829

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

Dated: July 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–18318 Filed 7–19–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0308]

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

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 requirements relating to the regulations of FDA's current good manufacturing practices (CGMP) and related regulations for blood and blood components, and ''lookback'' requirements.

DATES: Submit written or electronic comments on the collection of information by September 20, 2002.

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. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the docket number found in brackets in the heading of this document.

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: 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; and ''Lookback'' Requirements (OMB Control Number 0910–0116)—Extension

Under the statutory requirements contained in section 351 of 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. In addition, under the biologics licensing and quarantine provisions in sections 351 to 361 of the Public Health Service Act (42 U.S.C. 262 to 264) and the general administrative provisions under sections 501 to 503, 505 to 510, and 701 to 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 to 353, 355 to 360, and 371 to 374), FDA has the authority to issue regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the introduction, transmission, or spread communicable diseases. The CGMP and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The lookback regulations are intended to help ensure the continued safety of the blood supply by providing necessary information to users of blood and blood components and appropriate notification of recipients of transfusion at increased risk for transmitting human immunodeficiency virus (HIV) infection.

The information collection requirements in the CGMP and lookback 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 enables 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 (SOPs) 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. 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 606.110(b) requires establishments to request prior Center for Biologics Evaluation and Research (CBER) approval for plasmapheresis of donors who do not meet donor requirements. Section 606.151(e) (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, § 606.160 (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. Section 606.165 (21 CFR 606.165) requires 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 collection and transfusions be reported to FDA as soon as possible and that a written report shall be submitted within 7 days. Section 610.46(a) (21 CFR 610.46(a)) requires blood establishments to notify consignees, within 72 hours, of repeatedly reactive tests results so that previously collected blood and blood components are appropriately quarantined. Section 610.46(b) requires blood establishments to notify consignees of licensed, more specific test results for HIV within 30 calendar days after the donors's repeatedly reactive test. Section 610.47(b) (21 CFR 610.47(b)) requires transfusion services not subject to Centers for Medicare and Medicaid Services (CMS) regulations to notify physicians of prior donation recipients or to notify recipients themselves of the need for HIV testing and counseling. In addition to the CGMP's in 21 CFR part 606, there are regulations in part 640 (21 CFR part 640) that require additional standards for certain blood and blood components as follows: Sections 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 21 CFR 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 CMS.

Based on FDA's registration system, there are approximately 2,841 registered blood establishments inspected by FDA. Of these 2,841 establishments, approximately 1,349 perform pheresis, approximately 1,041 annually collect 27 million units of Whole Blood, blood components including Source Plasma, and Source Leukocytes and are required to follow FDA ''lookback'' procedures, and approximately 166 are registered transfusion services that are not subject to CMS's ''lookback'' regulations. Based on CMS records there are an estimated 4,980 transfusion services.

The following reporting and recordkeeping estimates are based on information provided by industry, CMS, and FDA experience. In table 1 of this document, we estimate that there are approximately 3,500 repeat donors that will test reactive on a screening test for HIV. We estimate that each repeat donor has donated two previous times and an average of three components were made from each donation. Under § 610.46(a) and (b), this estimate results in 21,000 (3,500 x 2 x 3) notifications of the HIV screening test results to consignees by collecting establishments for the purpose of quarantining affected blood and blood components, and another 21,000 (3,500 x 2 x 3) notifications to consignees of subsequent test results. 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 0910–0338.

In table 2 of this document, 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 CGMP and related regulations by using model SOP's developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

FDA estimates the burden of this collection of information 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)[2]	70	1	70	20	1,400
610.46(a)	1,041	20	21,000	0.17	3,570
610.46(b)	1,041	20	21,000	0.17	3,570
610.47(b)	166	0.7	116	1	116
Total					8,656

[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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b)[2]	249[5]	1	249	24	5,976
606.100(c)	249[5]	10	2,490	1	2,490
606.110(a)[3]	67[6]	5	335	0.5	168
606.151(e)	249[5]	12	2,988	0.083	248
606.160[4]	249[5]	2,169	540,000	0.5	270,000
606.165	249[5]	2,169	540,000	0.083	44,820
606.170(a)	249[5]	12	2,988	1	2,988
Total					326,690

[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 SOPs, are included in the estimate for § 606.100(b).
[3]The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4]The recordkeeping requirements in §§ 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(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.
[5]Five percent of CMS and FDA-registered blood establishments (0.05 x 4,890).
[6]Five percent of pheresis establishments (1,349).

Dated: July 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0309]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reclassification petitions for medical devices.

DATES: Submit written and electronic comments on the collection of information by September 20, 2002.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. 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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Reclassification Petitions for Medical Devices—21 CFR 860.123 (OMB Control Number 0910–0138)—Extension

FDA has the responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes (I, II, and III) to another class. The reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting classification from class III to class II or class I, if approved, provide an alternative route to the market in lieu