This total estimate of 609 total annual burden hours is based on the 1998 survey administration, in which 9,643 potential respondents were contacted to obtain 1,000 interviews.

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–25701 Filed 10–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1353]

Agency Information Collection Activities; Submission for OMB Review; 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 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 November 6, 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: 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices (CGMP) and Related Regulations for Blood and Blood Components (OMB 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 part 640 (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). 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.

In the **Federal Register** of July 6, 2000 (65 FR 41674), the agency requested comments on the proposed collections of information. No significant comments were received.

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 REPORTING BURDEN[1]

21 CFR Section[2]	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	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
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), 640.53(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: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1395]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medicated Feed Mill License

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 November 6, 2000.

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, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medicated Feed Mill License 21 CFR Part 515—(OMB Control Number 0910–0337)—Extension

Description: This rule sets forth the information to be included in a medicated feed mill license application and subsequent supplemental applications. In addition, it provides criteria for the approval and nonapproval of a medicated feed mill license application and the criteria for the revocation and/or suspension of a license. More specifically, § 515.10(b) specifies requirements for submitting a completed medicated feed mill license application, using Form FDA 3448. Section 515.11(b) specifies requirements for supplemental medicated feed applications for a change in ownership and/or a change in mailing address for the facility cite, using Form FDA 3448. Section 515.23 sets forth written requirements for voluntary revocation of a medicated feed mill license by a sponsor on the grounds that the facility