Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use; Proposed Rule
0910-xxxx
SUPPORTING STATEMENT

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information collection requirements contained in the proposed rule which would amend 21 CFR Parts 606, 610, 630, 640, 660, 820, and 1270 (Attachment A). These information collection requirements are listed below.

606.100(b)	Recordkeeping	Requires collecting establishments to establish, maintain, and follow written procedures for investigating product deviations, and for recordkeeping related to current good manufacturing practice (CGMP) and biological product standards.
606.160(e)	Recordkeeping	Requires collecting establishments to maintain a list identifying ineligible donors and to provide this list to appropriate personnel to prevent the collection of blood and blood components from such individuals.
630.10(b)	Reporting	Requires collecting establishments to provide to the donor educational material containing useful and current information concerning the relevant transfusion-transmitted infections.
630.10(c)	Recordkeeping	Requires collecting establishments to establish, maintain, and follow written procedures for identifying blood components that cannot be stored more than 24 hours.
630.10(i)(2)	Reporting	Requires collecting establishments to provide the donor with information concerning the donation procedure.
630.15(b)(6)(iii)	Recordkeeping	Requires collecting establishments to document the special characteristics of the donor's antibody and the need for plasmapheresis.
630.20(c)(3)	Recordkeeping	Requires the collecting establishment to document the recipient's medical need, which necessitates the collection of blood or blood components from a donor determined to be ineligible to donate.
640.72(a)(2)(i), (a)	Recordkeeping	Requires the collecting establishment to

(3), and (a)(4)		maintain for each donor records of initial and periodic examinations, tests, laboratory data, interviews, the donor's written statement of understanding, and the donor's good health.
640.73	Reporting	Requires collecting establishments to report fatal donor reactions associated with plasmapheresis, and adverse experiences related to the administration of an immunizing agent.

We are issuing this rule under the authority of sections 351 and 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262 and 264) (Attachment B) and the provisions of the Federal Food, Drug, and Cosmetic Act (the act), which apply to drugs and devices (21 U.S.C. 321 *et seq*.) (Attachment C).

Blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351 of the PHS Act, which requires that such products be licensed. To obtain a license, applicants must show that the collecting establishment meets all applicable standards designed to assure the continued safety, purity, and potency of the blood and blood components, and that the product is safe, pure, and potent.

Under section 361 of the PHS Act, we may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Blood and blood components are also drugs or devices, as those terms are defined in sections 201(g)(1) and 201(h) of the act. Since blood and blood components are drugs or devices generally subject to the act, collecting establishments must comply with the act's current good manufacturing practice provisions and related regulatory scheme.

2. Purpose and Use of the Information Collection

The information collected by the blood collecting establishment would be used by the collecting establishment to determine the eligibility of every donor to donate and the suitability of every donation for use in transfusion or for further manufacturing.

FDA is taking this action to help ensure the safety of the national blood supply and to help protect donor health by requiring collecting establishments to evaluate donors for factors that may adversely affect the safety, purity, and potency of blood and blood components or the health of a donor during the donation process.

The information collection for 21 CFR 630.6 (redesignated as proposed 21 CFR 630.40) is currently approved under OMB No. 0910-0116. All other proposed requirements are new collections of information.

3. Use of Improved Information Technology and Burden Reduction

All establishments may use computer tapes or discs, microfiche, or microfilm to record and store data and information rather than hard copy records if they choose. FDA is not aware of any improved information technology that could be used to reduce the burden except that blood establishments that are not automated could reduce the time required to maintain records with respect to input and retrieval by becoming computerized.

4. Efforts to Identify Duplication and Use of Similar Information

There are no other regulations requiring this information for this purpose. The required information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

FDA believes that its duty requires the equal application of the regulations to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, the agency does provide special help to small businesses. CBER's Office of Communication, Training and Manufacturers Assistance provides guidance to small businesses concerning regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

The collection or use of information occurs only as needed, i.e., at the time when a donor presents to donate. Less frequent collection of information would not ensure the safety, purity, and potency of the blood or blood component for use in transfusion or for further manufacturing. The information collected is necessary to fulfill FDA’s statutory responsibility to prevent the spread of communicable diseases. FDA would be unable to meet this responsibility with less frequent information collection.

There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of the information requirements.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we are providing a 30-day period for public comment on the information collection requirements of the proposed rule (72 FR 63416, November 8, 2007). FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of

FDA's function, 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.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any gift or payment to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information obtained under this program is subject to the regulations implementing the Freedom of Information Act, 21 CFR Part 20, "Public Information," when determining whether documents may be disclosed. After an FDA investigator completes a routine inspection of a blood or blood product manufacturing establishment, the completed report with the results of the inspection become public information, available upon request under the Freedom of Information Act. For example, completed inspection reports that are made available to the public have certain information, such as donor and patient names and addresses, which are redacted before the report would be released under the Freedom of Information Act and applicable FDA regulations.

11. Justification for Sensitive Questions

Establishments as part of the donor screening process for blood collection must ask questions of sensitive nature. These questions are used to evaluate the suitability of a donor. Donors not meeting certain criteria are deferred from donating. This information is necessary to help prevent the transmission of communicable diseases and protect public health. These records are maintained by the establishment and may be reviewed by FDA during an inspection.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 1,127,850 hours annually. FDA estimates the information collection burden as follows:

Table 1. -Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b) (Maintenance of SOPs)	1,709	1	1,709	24	41,016
606.160(e)	1,628	52	84,656	8	677,248
630.15 (b)(6)(iii)	81	1	81	0.17	14
640.72 (a)(2)(i), (a)(3), and (a)(4)	81	18,518.5	1,499,999	0.08	120,000
Total					838,278

Table 2. -Estimated Total First Year Recordkeeping Burden1

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b) (Creation of SOPs)	1,139 (379 annualized)	1	1,139	40	45,560 (15,187 annualized)
606.100(b) (Creation of SOPs)	570 (190 annualized)	1	570	56	31,920 (10,640 annualized)
630.10(c)	1,628 (542 annualized)	1	1,628	16	26,048 (8,683 annualized)
Total					103,528 (34,509 annualized)

[1]This table estimates one-time burden. The parenthetical numbers is the total first year burden, annualized.

Table 3. -Estimated Annual Reporting Burden

21 CFR Section	No. of Responses	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
630.10(i)(2)	81	18,518.5	1,499,999	0.17	255,000
640.73(a) and (c)	81	.037	3	20	60
640.73(b)	81	.037	3	1	3
Total					255,063

According to our registration database, there are currently about 1,709 establishments affected by this rule: approximately 81 licensed plasma establishments with multiple locations that collect Source Plasma, and approximately 1,628 registered blood

establishments that collect blood and blood components. Based on estimates provided by HHS and GAO, these establishments collect annually approximately 15 million units of Whole Blood, and approximately 13 million donations of Source Plasma.

Recordkeeping

As shown in table 1, for each of the 1,709 collecting establishments, we estimate that it will take approximately 24 hours annually to maintain the SOPs. We estimate in table 2 that two-thirds of 1,709 collecting establishments (1,139 / 379 annualized) will each expend, as a one-time burden, an average of 40 hours to reconcile their SOPs with the requirements, and the remaining one-third of the collecting establishments (570 / 190 annualized) would expend as a one-time burden an average of 56 hours to reconcile their SOPs with the requirements.

Also, as part of a one-time burden in table 2, 1,628 (542 annualized) blood collecting establishments would create a new SOP under proposed § 630.10(c), which we estimate will take 16 hours to create.

In table 1, under proposed § 606.160(e), Source Plasma collecting establishments are already providing to personnel a list identifying unsuitable donors as usual and customary business practice. Under proposed § 606.160(e), we estimate that it would take each blood-collecting establishment an average of 8 hours per week to update and provide their list (1,628 x 52 x 8 = 677,248). This estimated burden of 8 hours per week may appear to be lower or higher than the burden experienced by individual establishments. Since there is no available data, the burden is an estimated burden, taking into account the range of impact on each establishment. Some establishments may have the ability to generate the lists by computer; others may rely on manual preparation.

For proposed § 630.15(b)(6)(iii), Source Plasma collecting establishments would be permitted to collect plasma from a donor who is deferred due to red blood cell loss if the establishment documents the special characteristics of the antibody and the need for the plasmapheresis. Although we do not have data available, we believe that such a situation would occur infrequently. Consequently, we are estimating that each Source Plasma collecting establishment would have one occurrence per year and that it would take approximately 10 minutes (0.17 hours) to document the health of the donor and the special characteristics of the antibody and the need for the plasmapheresis.

Under proposed § 630.20(c)(3), donors who do not meet criteria under §§ 630.10, 630.15, or 610.41 would be permitted to donate under this proposed provision. Such donations, used solely by a specified recipient based on documented medical need, would occur rarely and, consequently, the burden to collecting establishments is negligible.

In proposed § 640.72(a)(2)(i), (a)(3), and (a)(4), we would require that Source Plasma collecting establishments maintain records for each donor of all examinations, tests, laboratory data, interviews, the donor's written statement of understanding and the donor's good health respectively. In table 1, we use GAO's estimate of approximately

1,500,000 donors that annually donate Source Plasma. We also estimate that the establishment would expend approximately 5 minutes (0.08 hours) for each donor.

Reporting

Proposed § 630.10(b), would require the collecting establishments to provide the donor with educational material. There is no calculated burden for this proposed requirement since establishments collecting blood and blood components perform this activity as usual and customary business practice.

The burden for proposed § 630.10(i)(2) in table 3 is only calculated for Source Plasma collecting establishments since the blood collecting establishments already provide the donor with a statement of understanding as usual and customary business practice. We estimate that approximately 81 Source Plasma collecting establishments would take an estimated 10 minutes (0.17) to perform this activity. Based on the GAO estimate of approximately 1,500,000 donors that annually donate Source Plasma, the total annual burden would be 255,000 hours (1,500,000 x 0.17).

Proposed § 640.73(a) would require 81 Source Plasma collecting establishments to report fatalities associated with plasmapheresis. We estimate that approximately 3 fatalities would be reported annually. A written follow-up report would also be required under § 640.73(c). Approximately 20 hours is estimated for both the initial and follow-up report.

Proposed § 640.73(b) would require Source Plasma collecting establishments to report any serious or life threatening adverse reaction experienced by a donor after administration with an immunization agent. Although we do not have access to data regarding such reports, we estimate that approximately 3 serious or life-threatening adverse reactions would occur annually, and that the establishment would expend approximately one hour to complete the initial and follow-up reports.

In this rulemaking, we are redesignating current § 630.6 as proposed § 630.40, which requires the collecting establishment to notify a donor when the donor is deferred from donation. Current § 630.6 is approved under OMB No. 0910-0116. This approval expires December 31, 2008.

We are not calculating information collection burden for § 640.120, because by permitting industry to use alternatives in complying with certain regulations for blood and blood components, we believe that this regulation reduces burden on industry.

Costs to Respondents

Activity	No. Of Hours	Cost per Hour	Total Cost
Recordkeeping (One-time burden)	103,528	$31	$3,209,368
Total	103,528		$3,209,368
Reporting (Annual burden)	255,063	$31	$7,906,953
Recordkeeping (Annual burden)	838,278	$31	$25,986,618
Total	1,093,341		$33,893,571

The total cost to the respondents the first year is estimated at approximately $37,102,939 based on the following information. An establishment's medical technologist, at $31 per hour, will expend approximately 1,196,869 hours on reporting and recordkeeping responsibilities. After the first year, the costs will not include those for establishing written procedures, i.e., 103,528 hours. Therefore, 1,093,341 hours is estimated as the ongoing annual burden related to these regulations ($33,893,571). The salary estimate includes benefits but no overhead cost.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital and start-up, and operation maintenance and purchase costs associated with the collection of information requirements.

14. Annualized Cost to the Federal Government

Compliance with these regulations will be reviewed by FDA during routine inspection of the establishments. The cost estimate to FDA for routine inspections may be found in OMB No. 0910-0116.

15. Explanation for Program Changes or Adjustments

FDA is taking this action to help ensure the safety of the national blood supply and to help protect donor health by requiring collecting establishments to evaluate donors for factors that may adversely affect the safety, purity, and potency of blood and blood components or the health of a donor during the donation process.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt the display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.