Requirements for Blood and Blood Components
Intended for Transfusion or for Further Manufacturing Use – Final Rule

0910-0795

RIN #: 0910-AG87

SUPPORTING STATEMENT

Terms of Clearance: The information collection requirements associated with the proposed rule are not approved at this time. FDA will consider comments received and resubmit at the final rule stage.

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 21 CFR Parts 606, 630, and 640. These information collection requirements are listed below.

21 CFR Section	Category	Description
606.100(b)	Recordkeeping	Requires collecting establishments to establish, maintain, and follow written procedures for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for allogeneic transfusion, autologous transfusion, and further manufacturing purposes; for all steps in the investigation of certain product deviations, and for all steps in recordkeeping related to current good manufacturing practice (CGMP) and other applicable requirements and standards.
606.100(b)(22)	Recordkeeping	Requires that blood collection establishments and transfusion services must have procedures to control the risk of bacterial contamination of platelets, including all steps required under § 606.145.
606.145(c)	Disclosure	Requires transfusion services, in the event a transfusion service identifies platelets as bacterially contaminated, to notify the blood collection establishment that provided the platelets. The transfusion service must further notify the blood collection establishment either by providing information about the identity of the species of the contaminating organism or

		by advising the blood collection establishment that the species cannot be identified.
606.160(b)(1)(i)	Recordkeeping	Requires collection establishments to maintain donor records that include donor selection, including medical interview and examination and where applicable, informed consent.
630.15(a)(1)(ii)(B)	Recordkeeping	Requires that for a dedicated donation based on the intended recipient's documented exceptional medical need, collecting establishments document the exceptional medical need and the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.
630.20(c)	Recordkeeping	Requires the collecting establishment to document the recipient's exceptional medical need, which necessitates the collection of blood or blood components from a donor determined to be ineligible to donate, and requires that the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue medical risk to the transfusion recipient.
640.72(a)(4)	Recordkeeping	Requires the collecting establishment to maintain records of the medical history and physical examination of the donor conducted in accordance with § 630.15(b)(1) and, where applicable, § 630.15(b)(5), and must document the eligibility of the donor as a plasmapheresis donor, and, when applicable, as an immunized donor.

In addition to the above requirements, there are recordkeeping requirements in the following regulations: §§ 606.110(a)(2); 606.160(e); 606.171; 630.5(b)(1)(i); 630.5(d); 630.10(c)(1) and (c)(2); 630.10(f)(2) and (f)(4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (a)(1)(ii)(B); 630.15(b)(2); 630.15 (b)(7)(i) and (b)(7)(iii); 630.20(a) and (b); and 640.21(e)(4). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described in section 12, below.

FDA is issuing this rule under the authority of sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264), and certain provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that apply to drugs and devices (21 U.S.C. 321 *et seq*.).

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 manufacturing establishment meets all applicable standards designed to assure the continued safety, purity, and potency of the blood and blood components, and that the biological product is safe, pure, and potent.

Under section 361 of the PHS Act, FDA makes and enforces 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 FD&C Act. Since blood and blood components are drugs or devices generally subject to the FD&C Act, collecting establishments must comply with the FD&C Act's current good manufacturing practice provisions and related regulatory scheme.

2. Purpose and Use of the Information Collection

This information collection requires recordkeeping from establishments that collect blood and blood components and transfusion services to establish and maintain procedures and records for donors and the collection, processing, testing, storage, and distribution of blood and blood components. This information also requires notification to certain blood collection establishments concerning bacterial contamination of platelets.

The information collection required by these regulations would be used by the collecting establishment to help ensure that a donor of blood and blood components is free of infectious disease, in good health, and eligible to donate without adversely affecting the health of the donor. In addition, the information collection would be used by the collecting establishment to determine that donations are suitable for transfusion or further manufacture.

FDA is taking this action to better ensure the safety of the nation's blood supply by making the donor eligibility and testing requirements more consistent with current practices in the blood industry, aligning the regulations more closely with current FDA recommendations, and providing flexibility to accommodate advancing technology.

3. Use of Improved Information Technology and Burden Reduction

The information collections, may be accomplished by use of automated, electronic, mechanical, or other technological collection techniques or forms of information technology made electronically. Advanced methods of recordkeeping (e.g., by an electronic method) improve the ability of collecting establishments to easily maintain and retrieve, records of donor eligibility and donation suitability determinations. FDA is not aware of any other improved technology to reduce the burden.

FDA estimates that 95% of the respondents will use automated, electronic, and mechanical means to fulfill the agency's requirements or requests.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires this information. There is no similar information available from any other source.

5. Impact on Small Businesses or Other Small Entities

This collection of information applies to small as well as large facilities. Although FDA must equally apply the statutory and regulatory requirements to all enterprises, FDA does provide help to small businesses. CBER's Office of Communication, Outreach, and Development, Division of Manufacturer's Assistance and Training provides assistance to small businesses concerning FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

The collection or use of information occurs only as needed to ensure the eligibility and safety of a donor and the suitability of the donation.

Less frequent information collection would not provide the information necessary for collecting establishments to ensure that a donor is free of infectious disease, in good health, and eligible to donate without adversely affecting the health of the donor; and that the donation is suitable for transfusion or further manufacture. In addition, the information collected is necessary to fulfill FDA's statutory responsibility to act to prevent the spread of communicable diseases. FDA would be unable to meet this obligation with less frequent information collection.

There are no legal obstacles to reduce the burden.

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

There are no special circumstances for this collection of information.

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

In accordance with 21 CFR 1320.8(d), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of 11/08/2007 (72 FR 63416). FDA received two letters of comments concerning the information collection burden estimate for § 606.160(e) and the possible effect of the information collection on capital costs or operating and maintenance costs.

FDA does not consider the comments to present any issues to be resolved because the requirements under § 606.160(e), have been revised in this final rule to narrow the scope of the recordkeeping requirement and reduce the collection of information burden. Further, the requirements under § 606.160(e) in this final rule do not create additional capital costs or operating and maintenance costs.

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 ensure that a donor is free of infectious disease, in good health, and eligible to donate without adversely affecting the health of the donor; and that the donation is suitable for transfusion or further manufacture. Establishments are required to provide educational material concerning relevant transfusion-transmitted infections to donors before donation and obtain informed consent, where applicable. Donors not meeting certain criteria are deferred from donating.

This information is necessary to help prevent the transmission of relevant transfusion-transmitted infections 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

12a. Annualized Hour Burden Estimate

The total annual estimated burden for information collection is 7,283,556 hours. FDA estimates the information collection burden as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]					
21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
606.100(b) (Maintenance of SOPs)[2]	2,361	1	2,361	24	56,664
606.100(b) (Maintenance of SOPs)[3]	4,961	1	4,961	10	49,610
606.160(b)(1)(i)[4] Records (General)	2,361	16,942	40,000,000	0.17	6,800,000
630.15(a)(1)(ii)(B) Donor Eligibility	1,945	1	1,945	1	1,945
630.20(c) Donor Exceptions	1,945	1	1,945	1	1,945
640.72(a)(4) Records (SourcePlasma)	416	4,808	2,000,000	0.08	160,000
Total					7,070,164

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

[2] The recordkeeping requirements in §§ 606.171, 630.5(d), and 630.10(c)(1) and (c)(2) are included in the estimate for § 606.100(b).

[3] The recordkeeping requirements in § 606.100(b)(22) is included in the estimate for § 606.100(b).

[4] The recordkeeping requirements in §§ 606.110(a)(2); 606.160(e); 630.5(b)(1)(i); 630.10(f)(2) and (f)(4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (a)(1)(ii)(B); 630.15(b)(2), (b)(7)(i) and (b)(7)(iii); 630.20(a) and (b); and 640.21(e)(4), are included in the estimate for § 606.160(b)(1)(i).

TABLE 2.— ESTIMATED ONE-TIME RECORDKEEPING BURDEN[1]					
21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record	Total Hours
606.100(b) (Review and Modify SOPs)[2]	525 (1,574)	1	525 (1,574)	40	20,986 (62,960)
606.100(b) (Review and Modify SOPs)[2]	262 (787)	1	262 (787)	60	15,740 (47,220)
606.100(b) (Review and Modify SOPs)	1,654 (4,961)	1	1,654 (4,961)	16	26,459 (79,376)
606.100(b)(22) (Establish SOPs)	496 (1,488)	1	496 (1,488)	16	7,936 (23,808)
Total					71,121 (213,364)

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The recordkeeping requirements in §§ 606.171; 630.5(d); and 630.10(c)(1) and (c)(2), are included in the estimate for § 606.100(b).

In Table 2 the No. of Recordkeepers, Total Annual Records and Total Hours have been divided by three for the purpose of entering one-time burden into ROCIS. The top number represents the annualized one-time burden (because we desire a three year approval of the information collection) while the parenthetical number represents the entire one-time burden.

TABLE 3.—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]					
21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
606.145(c) Notification of Bacterial Contamination	4,961	0.28	1,400	0.02	28

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

Respondents to this collection of information include licensed and unlicensed, registered blood establishments that collect blood and blood components for transfusion, licensed blood

establishments that collect Source Plasma, and registered and unregistered transfusion services.

Recordkeeping

As shown in Table 1, under § 606.100(b), FDA estimates that for the 2,361 recordkeepers, which includes approximately 1,265 licensed blood collection establishments, approximately 416 licensed Source Plasma establishments, and approximately 680 total unlicensed, registered blood collection establishments, it will take approximately 24 hours annually to review and maintain SOPs. The recordkeeping requirements in §§ 606.171, 630.5(d), and 630.10(c)(1) and (2) are included in the estimate for § 606.100(b).

In addition, the information collection burden under § 606.100(b)(22), for the transfusion services to maintain their SOPs is included in the information collection burden estimate under § 606.100(b).

The information collection burden for §§ 606.110(a)(2); 606.160(e); 630.5(b)(1)(i); 630.10(f)(2) and (4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (B); 630.15(b)(2), (b)(7)(i) and (b)(7)(iii); 630.20(a) and (b); and 640.21(e)(4), refer to the requirement to maintain records for donor selection under § 606.160(b)(1) specifically § 606.160(b)(1)(i) and are included in the information collection burden estimate under this regulation.

In Table 1 of this document, under § 630.15(a)(1)(ii)(B) and § 630.20(c), FDA calculates the information collection burden that for the 1,945 recordkeepers, which includes approximately 1,265 licensed blood collection establishments and approximately 680 registered blood collection establishments. The donation would be used solely by a specified recipient based on documented medical need, and thus would occur rarely. Consequently, the burden to collection establishments is minimal.

The revisions to § 606.160(b)(1)(ix) through (xi) are technical amendments and do not result in any new information collection burden. The information collections for these sections have been approved under OMB control number 0910–0116.

FDA is not calculating the information collection burden for final § 606.100(b)(20) and (21) because these regulations have not been changed only redesignated. The information collection for final § 606.100(b)(20) and (21) have been approved under OMB control number 0910–0116.

Under § 606.160(e), FDA is not calculating the information collection burden specifically for establishments to maintain donor records because there is either minimal or no additional burden associated with the final § 606.160(e) because establishments have either been maintaining these records or providing access to these records at locations operating under the same license or under common management under current regulation(s) or guidance(s), or as part of their usual and customary business practice. In addition, the number of ineligible donors for which the establishments must maintain records has been decreased from the proposed rule in this final rule, which reduces the information collection burden for

this requirement. The information collection for § 606.160(e) have been approved as part of § 606.160 under OMB control number 0910–0116.

FDA is not calculating the information collection burden for § 640.72(a)(2)(i), because the information collection for maintaining a complete record of all initial and periodic examinations, tests, laboratory data, interviews, etc., for final § 630.10 (redesignated from § 640.63) and §§ 640.65, 640.66, and 640.67 have been approved under OMB control number 0910–0116. In addition, the information collection cross-referenced under § 630.15, is included in the information collection burden estimate for § 606.160(b)(1)(i). FDA is not calculating the information collection burden for § 640.72(a)(2)(ii), because there is no additional burden and is covered under OMB control number 0910–0116.

As shown in Table 2 of this document, under § 606.100(b), FDA estimates that for the 2,361 recordkeepers, two-thirds or 1,574 of the collection establishments will each expend, as a one-time burden, to reconcile their SOPs with the requirements. FDA estimates for the remaining one-third or 787 of the collection establishments each will expend additional time to establish and reconcile their SOPs with the requirements. The one-time recordkeeping requirements in §§ 606.171, 630.5(d), and 630.10(c)(1) and (2) are included in the estimate for § 606.100(b).

In Table 2 of this document, under § 606.100(b)(22), FDA estimates that for the 4,961 transfusion services potentially impacted by this rule, 40 percent are following the voluntary standards for testing, speciation, and notifying the blood establishment, as usual and customary practice. For the remaining 60 percent (2,977) transfusion services, approximately one-half (1,488) would be impacted by the rule and each of these would expend, as a one-time burden, and to create SOPs consistent with the requirements.

Third Party Disclosure

In Table 3 of this document, under § 606.145(c), FDA estimates that for the approximate 4,961 transfusion services, there would be 1,400 total notifications per year to blood collection establishments (700 notifications per year that platelets are bacterially contaminated and 700 notifications per year concerning the identity or non-identity of the species of the contaminating organism).

The labeling requirements under § 630.15(a)(2), are consistent with the current requirement under § 640.3(d) that donations from a donor "shall not be used as a source of Whole Blood unless the container label conspicuously indicates the donor's disease that necessitated withdrawal of blood." FDA is not calculating the information collection burden for § 630.15(a)(2) because the burden is included in the calculation for § 640.3(d). In addition, § 630.15(a)(2) reduces the information collection burden by not requiring labeling under the conditions specified in the regulation. The information collection burden in § 630.40(d) is approved under OMB control number 0910–0116.

Under § 630.10(b), FDA requires collection establishments to provide the donor with educational material. FDA is not calculating the information collection burden for this

regulation because establishments collecting blood and blood components perform this activity as a usual and customary business practice and there is minimal new information collection burden for this requirement.

The information collection burden in final § 630.40 resulting from the redesignation of § 630.6 has been approved under OMB control number 0910–0116. Under final § 630.40, FDA considers the changes in text from: *"communicable disease"* to *"relevant transfusion-transmitted infection(s)"*, *"suitable"* to *"eligible"*, *and "suitability"* to *"eligibility"*, to be technical amendments that do not confer any new burden. FDA is not calculating the information collection burden under § 606.145(d) for the additional requirement that establishments that collect blood or blood components make reasonable attempts to notify any donor whose donated platelets have been determined to be contaminated with an organism that is identified as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor, because establishments perform this activity as a usual and customary business practice and there is minimal new information collection burden for this requirement. The third party disclosure burden under § 630.30(b)(4), is covered under § 630.40.

Under § 640.21(c), FDA requires the establishments to label donations received from platelet donors who have recently ingested a drug that adversely affects platelet function to identify the ingested drug. FDA is not calculating the information collection burden for this regulation as there is minimal additional burden for this requirement because establishments collecting blood and blood components perform this activity as a usual and customary business practice.

The collections of information under § 640.120 has been approved under OMB control number 0910-0338. FDA is not calculating information collection burden for § 640.120, because the changes that were made will not have an impact on the current burden estimated for industry.

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is $325,388,861.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Medical Technologist	5,429,180	$40.00	$217,167,200
Medical Supervisor	1,447,782	$53.00	$76,732,446
Medical Director	361,945	$87.00	$31,489,215
Total			$325,388,861

The cost is based on an estimated pay rate of $40/hour for a medical technologist, who is responsible for recording donor, quarantine, testing, and disposition of information, notifying consignees of test results, and has the training and skills to handle various recordkeeping requirements. The cost estimate is also based on a pay rate of $53/hour for a supervisor who is responsible for updating SOPs, recording donor information, and notifying physicians of recipients or recipients of test results, investigating, writing, and reporting a fatality; and on a pay rate of $87/hour for a medical director who is responsible for updating SOPs, recording donor information, and notifying physicians of recipients or recipients of test results, investigating, writing, and reporting a fatality. These salary estimates include benefits but no overhead costs.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Compliance with these regulations will be reviewed by FDA during routine inspection of the establishments. The estimated annualized cost to the Federal Government is $2,548,800. This estimate is based on a FDA reviewer or investigator at an average grade scale of GS-12/5 ($54/hour), who performs biannual on-site inspections. The inspection cost includes inspection of a facility, review of facility records, and report preparation. These salary estimates include benefits but no overhead costs.

Activity	Number of Respondents	Number of Hours	Cost per Hour	Total Cost
Inspection	1,180	40	$54	$2,548,800

15. Explanation for Program Changes or Adjustments

Program changes or adjustments are not applicable as this is the first submission of the final rule. This is a new information collection.

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

There are no exceptions to the certification.