OMB INFORMATION COLLECTION
SUPPORTING STATEMENT

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and "Lookback"
0910-0116

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of Office of Management and Budget (OMB) Control No. 0910-0116 and OMB approval of the information collection requirements as listed below:

21 CFR 606.100(b)	Recordkeeping	Requires that written standard operating procedures (SOPs) be maintained for all steps to be followed in the collection, processing, compatibility testing, storage and distribution of blood and blood components used for transfusion and further manufacturing purposes.
21 CFR 606.100(c)	Recordkeeping	Requires the review of all records pertinent to the lot or unit of blood prior to release or distribution. Any unexplained discrepancy or the 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 follow-up, must be recorded.
21 CFR 606.110(a)	Recordkeeping	Provides that the use of plateletpheresis or leukapheresis procedures to obtain a product for a specific recipient may be at variance with the additional standards for that specific product, if among other things, the physician certifies in writing that the donor's health permits plateletpheresis or leukapheresis.
21 CFR 606.121	Disclosure	Requires container label for blood and blood components (except Source Plasma) by all blood establishments.
21 CFR 606.122	Disclosure	Requires an instruction circular to provide adequate directions for use, to be available for distribution if the product is intended for transfusion.
21 CFR 606.151(e)	Recordkeeping	Requires that SOPs for compatibility testing include procedures to expedite transfusion in life-threatening emergencies; records of all such incidents must be maintained, including complete documentation

		justifying the emergency action
21 CFR 606.160	Recordkeeping	Requires that legible and indelible contemporaneous records of each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components be made and maintained for no less than 10 years.
21 CFR 606.160(b)(1)(viii)	Recordkeeping	Requires maintenance of records concerning quarantine, notification, testing and disposition performed under the human immunodeficiency virus (HIV) and hepatitis C virus (HCV) ‘‘lookback’’ provisions.
21 CFR 606.160(b)(1)(ix)	Recordkeeping	Requires a blood collection establishment to maintain records of notification of donors deferred or determined not to be eligible for donation, including appropriate follow-up.
21 CFR 606.160(b)(1)(xi)	Recordkeeping	Requires an establishment to maintain records of notification of the referring physician of a deferred autologous donor, including appropriate follow-up.
21 CFR 606.165	Recordkeeping	Requires that distribution and receipt records be maintained to facilitate recalls, if necessary.
21 CFR 606.170(a)	Recordkeeping	Requires records to be maintained of any reports of complaints of adverse reactions arising as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and follow-up, must be prepared and maintained. When an investigation concludes that the product caused the transfusion reaction, copies of all such written reports must be forwarded to written reports must be forwarded to and maintained by the manufacturer or collecting facility.
21 CFR 606.170(b)	Reporting	Requires that fatal complications of blood collection and transfusion be reported to FDA’s Center for Biologics Evaluation and Research (CBER) as soon as possible after confirming a complication of blood collection or transfusion. The collecting facility is to report donor fatalities, and the compatibility testing facility is to report recipient fatalities. The reporting facility also must submit a written report of the investigation within 7 days after the fatality.
21 CFR 610.40(c)(1)(ii)	Reporting	Requires that each donation dedicated to a single identified recipient be labeled as required under § 606.121, and with a label entitled “INTENDED RECIPIENT INFORMATION LABEL” containing the name and identifying information of the recipient.
21 CFR 610.40(g)	Recordkeeping	Requires an establishment to appropriately document

(1)		a medical emergency for the release of human blood or blood components prior to completion of required testing.
21 CFR 610.40(g)(2)	Reporting	Requires an establishment to obtain written approval from FDA to ship human blood or blood components for further manufacturing use prior to completion of testing for evidence of infection due to certain communicable disease agents.
21 CFR 610.40(h)(2)(ii)(A)	Reporting	Requires, in brief, an establishment to obtain written approval from FDA to use or ship human blood or blood components found to be reactive by a screening test for evidence of certain communicable disease agent(s) or collected from a donor with a record of a reactive screening test.
21 CFR 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	Reporting	Require an establishment to label certain reactive human blood and blood components with the appropriate screening test results, and, if they are intended for further manufacturing use into injectable products, include a statement on the label indicating the exempted use specifically approved by FDA.
21 CFR 610.40(h)(2)(vi)	Reporting	Requires each donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results.
21 CFR 610.42(a)	Reporting	Requires a warning statement, “indicating that the product was manufactured from a donation found to be reactive by a screening test for evidence of infection due to the identified communicable agent(s)” in the labeling for medical devices containing human blood or a blood component found to be reactive by a screening test for evidence of infection due to a communicable disease agent(s) or syphilis.
21 CFR 610.46(a)(1)(ii)(B) and 610.47(a)(1)(ii)(B)	Reporting Disclosure	Requires a collecting establishment, within 3 calendar days of the donor testing reactive by an HIV or HCV screening test or the collecting establishment becoming aware of other reliable test results or information, to, among other things, notify consignees to quarantine all identified previously collected in-date blood and blood components.
21 CFR 610.46(a)(3) and 610.47(a)(3)	Reporting Disclosure	Requires a collecting establishment, within 45 calendar days of the donor testing reactive by an HIV or HCV screening test, to, among other things, notify consignees of supplemental test results, or the results of a reactive screening test if there is no available

		supplemental test that is approved for such use by FDA.
21 CFR 610.46(b) and 610.47(b)	Reporting-Disclosure	Requires consignees to establish, maintain, and follow an appropriate system for performing HIV and HCV ''lookback'' when notified by the collecting establishment that they have received blood and blood components previously collected from donors who later tested reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection in a donor. This provision for a system requires the consignee to establish SOPs for, among other things, notifying transfusion recipients of blood and blood components, or the recipient's physician of record or legal representative, when such action is indicated by the results of the supplemental (additional, more specific) tests or a reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or an investigational device exemption (IDE), is exempted for such use by FDA.
21 CFR 610.46 (b) (3) and 610.47(b)(3)	Reporting	Requires the consignee to make reasonable attempts to perform the notification within 12 weeks of receipt of the supplemental test result or receipt of a reactive screening test result when there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA.
21 CFR 630.6(a)	Reporting	Requires an establishment to make reasonable attempts to notify any donor who has been deferred as required by § 610.41, or who has been determined not to be eligible as a donor.
21 CFR 630.6(d)(1)	Reporting	Requires an establishment to provide certain information to the referring physician of an autologous donor who is deferred based on the results of tests as described in § 610.41.

In addition to the current good manufacturing practice (CGMP) regulations in part 606 (21 CFR part 606), there are recordkeeping requirements in part 640 (21 CFR part 640) as follows: §§ 640.3(a)(1), (a)(2), and (f); 640.4(a)(1) and (a)(2); 640.25(b)(4) and (c)(1); 640.27(b), 640.31(b), 640.33(b), 640.51(b), 640.53(b) and (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 in section 12, below.

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further manufacture into injectable products, have a license, issued upon a demonstration that the product is safe, pure and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA 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.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic (FD&C) Act also applies to biological products. Blood and blood components for transfusion or for further manufacture into injectable products are drugs, as that term is defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the FD&C Act. For example, under section 501 of the FD&C Act (21 U.S.C. 351(a)), drugs are deemed “adulterated” if the methods used in their manufacturing, processing, packing, or holding do not conform to CGMP and related regulations.

The CGMP and related regulations implement FDA’s statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donors for evidence of infection due to communicable disease agents and in notifying donors is to prevent the transmission of communicable disease. For example, the “lookback” requirements 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 who are at increased risk for transmitting HIV or HCV infection.

2. Purpose and Use of the Information Collection

The CGMP regulations (part 606) (21 CFR part 606)) and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donors for evidence of infection due to communicable disease agents and in notifying donors is to prevent the transmission of communicable disease. For example, the “lookback" requirements 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 who are at increased risk for transmitting HIV or HCV infection.

The information collection requirements in the CGMP, donor testing, donor notification, and “lookback” requirements 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 preventive 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. Consignee notification ensures that the prior collections of blood and blood components are appropriately quarantined. Recipient notification provides an opportunity for counseling, appropriate testing, early treatment and precautions necessary to prevent further spread of a communicable disease. The reporting requirements inform FDA of any deviations that occur and that may require immediate corrective action.

FDA allows the use of shipment prior to test results of human blood or blood components under two circumstances: appropriately documented medical emergency situations or for further manufacturing use as approved in writing by FDA. Use or shipment prior to test results may occur, provided the consignee is notified that test results are not available, the tests for evidence of infection due to communicable disease agents are performed as soon as possible after release or shipment, and the results are provided promptly to the consignee. The regulations require an establishment to document the emergency release or shipment of blood or blood components prior to completion of testing. If the establishment ships blood or blood components for further manufacturing use prior to completion of testing, the establishment must obtain prior approval from FDA. In either instance, the establishment must complete testing as soon as possible thereafter, and must notify the consignee of test results as soon as they are available. Prior approval is necessary to help ensure that an establishment is following proper procedures in shipping potentially infectious blood and blood components for further manufacturing use. Without this information, FDA could not monitor industry procedures and discharge its statutory responsibility for protecting the nation's health.-

The donor notification process is intended to prevent further donations from donors who have been deferred for positive test results for markers of certain communicable disease agents(s) as prescribed in § 610.41 or for failing to satisfy the donor eligibility criteria under §§ 640.3 or 640.63 prior to collection. Deferred donors are informed of: (1) the reason for the decision; (2) the types of donation that the donor should not donate in the future, if appropriate; (3) the results of the tests for evidence of infection due to communicable disease agents that were the basis for deferral, if applicable; and (4) information concerning medical follow-up and counseling. By having this information, the deferred donor may make informed decisions as to his or her medical welfare.

3. Use of Improved Information Technology and Burden Reduction

Establishments may use computer tapes, discs, microfiche or microfilm in lieu of hard copy records for the purpose of maintaining records. Computers may be used for emailing reports to FDA. Notification of consignees can be accomplished by email, phone, fax, or mail.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requests this information. There is no similar kind of information 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, FDA does provide special help to small businesses. CBER's Office of Communication, Training and Manufacturer's Assistance provides assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Less frequent information collection would not provide the information necessary for blood establishments to perform the "lookback" procedures, and for FDA to monitor the establishment procedures and ensure the safety of the nation's blood supply. Records are reviewed at the time of inspection for compliance with FDA regulations and for any appropriate corrective action. Initial preparation of SOPs is a one-time burden.

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), a 60-day notice for public comment on the information collection provisions was published in the Federal Register of June 24, 2008 (73 FR 35694). We received one public comment on the proposed information collection.

The comment cited numerous problems that it stated were caused by the labeling requirement contained in § 610.40(h)(2)(vi), which requires each donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results. For example, the comment stated that the labeling requirement "causes unnecessary work and interrupts routine operations, thereby introducing risk of error, with no increase in safety.'' The comment also stated that the requirement "generates inappropriate concerns on the part of healthcare personnel, transfusion recipients and their families." The comment asked that this requirement be deleted. These concerns pertain to matters that are outside the scope of the proposed information collection. Consequently, we decline to adopt the comment's recommendations.

The comment also questioned FDA's estimate of five minutes in connection with § 610.40(h)(2)(vi). We had estimated that the time associated with the labeling requirement contained in this rule was five (4.8) minutes. The comment stated, "Any non-routine activity that interrupts normal labeling operations, [sic] causes delays that take more than 4.8 minutes." The comment later went on to acknowledge that the application of a label to a unit, which is only one step in

the labeling process, may take only five minutes. We wish to clarify that we only are referring to the application of a label to a unit in this proposed information collection. Therefore, consistent with the comment, our estimate remains the same.

Moreover, the comment referred to page 35697 of the June 24, 2008, Federal Register notice and Table 1 in the notice, and stated that "FDA estimated that labeling directed and reactive or untested units for shipment would take five minutes. If labeling refers only to the application of the label to the unit, which is only one step in the labeling process, then 5 minutes may be adequate." We are unclear what the comment is referring to on page 35697 of the Federal Register notice and note that Table 1 refers to an estimate of 0.08 (4.8 minutes) with respect to §§ 610.40(c)(1)(ii), 610.40(h)(2)(vi), and 630.6(a). We are assuming that the comment is referring to the first two regulations, as the third goes to donor notification. We wish to clarify that in this information collection, we are only referring to the application of the label to the unit. Therefore, consistent with the comment, our estimate remains the same.

Finally, the comment pointed out an error in calculation of total hours associated with § 606.160(b)(1)(ix) in Table 2. The total hours calculated was listed as 875,000, instead of 87,500 (0.05 x1,750,000). We have corrected this error accordingly.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA would be consistent with the Freedom of Information (FOI) Act and the agency's regulations under 21 CFR Part 20. After an FDA investigator completes a routine inspection of a blood or blood component manufacturing establishment, the completed report with the results of the inspection become public information, available under the FOI Act. However, certain information, such as donor and patient names, for example, is deleted from any information released by FDA under the FOI Act and FDA regulations. Manufacturers of human blood and blood components are not required to reveal any proprietary information or trade secrets to achieve compliance with the provisions.

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 426,913 hours.

Table 1. – Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(a)	353[4]	1.20	424	0.5	212
606.170(b)[1]	100	1	100	20	2,000
610.40(c)(1)(ii)	2,081	5.77	12,000	0.08	960
610.40(g)(2)	1	1	1	1	1
610.40(h)(2)(ii)(A)	1	1	1	1	1
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	40	12	480	0.2	96
610.40(h)(2)(vi)	2,081	8.65	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	2,000	5.25	10,500	0.17	1,785
610.46(a)(3)	2,000	5.25	10,500	0.17	1,785
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
610.47(a)(1)(ii)(B)	2,000	11.70	23,400	0.17	3,978
610.47(a)(3)	2,000	11.70	23,400	0.17	3,978
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
630.6(a)[2]	667	644.68	430,000	0.08	34,400
630.6(a)[3]	104	43.27	4,500	1.5	6,750
630.6(d)(1)	100	30	3,000	1	3,000
Total					64,487

[1] The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

[2] Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.

[3] Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

TABLE 2. -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)[1]	353[3]	1	353	24	8,472
606.100(c)	353[3]	10	3,530	1	3,530
606.110(a)[2]	35[4]	1	35	0.5	18
606.151(e)	353[3]	12	4,236	0.083	352
606.160[3]	353[3]	793.20	280,000	0.75	210,000
606.160(b)(1)(viii)					
HIV consignee notification	2,000 4,980	10.50 4.21	21,000 21,000	.17 .17	3,570 3,570
HCV consignee notification	2,000 4,980	23.40 9.4	46,800 46,800	.17 .17	7,956 7,956
HIV recipient notification	4,980	0.35	1,755	.17	298
HCV recipient notification	4,980	0.41	2,050	.17	349
606.160(b)(1)(ix)	2,081	840.94	1,750,000	0.05	87,500
606.160(b)(1)(xi)	2,000	3.375	6,750	0.05	338
606.165	353[3]	793.20	280,000	0.083	23,240
606.170(a)	353[3]	12	4,236	1.00	4,236
610.40(g)(1)	2,081	1	2,081	0.5	1,041
Total					362,426

[1] 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).

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

[3] The recordkeeping requirements in §§ 640.3(a)(2) and (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 (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.

[4] Five percent of establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 that transfuse blood and components and FDA-registered blood establishments (0.05 x 4,980 + 2,081).

[5] Five percent of plateletpheresis and leukopheresis establishments (0.05 x 696).

Respondents to this collection of information are licensed and unlicensed blood establishments

that collect blood and blood components, including Source Plasma and Source Leukocytes, inspected by FDA, and other transfusion services inspected by Centers for Medicare and Medicaid Services (CMS). Based on information received from CBER's database systems, there are approximately 81 licensed Source Plasma establishments with multiple locations and approximately 2,000 registered blood collection establishments, for an estimated total of 2,081 establishments. Of these establishments, approximately 696 perform plateletpheresis and leukopheresis. These establishments annually collect approximately 28 million units of Whole Blood and blood components, including Source Plasma and Source Leukocytes, and are required to follow FDA ''lookback'' procedures. In addition, there are another 4,980 establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 (formerly referred to as facilities approved for Medicare reimbursement) that transfuse blood and blood components.

The reporting and recordkeeping estimates are based on information provided by industry, CMS, and FDA experience. Based on information received from industry, we estimate that there are approximately 13 million donations of Source Plasma from approximately 2 million donors and approximately 15 million donations of Whole Blood, including 300,000 (2% of 15 million) autologous donations, from approximately 8 million donors. Assuming each autologous donor makes an average of 2 donations, FDA estimates that there are approximately 150,000 autologous donors.

FDA estimates that approximately 5 percent (12,000) of the 240,000 donations that are donated specifically for the use of an identified recipient would be tested under the dedicated donors testing provisions in § 610.40(c)(1)(ii).

Under § 610.40(g)(2) and (h)(2)(ii)(A), the only product currently shipped prior to completion of testing for evidence of certain communicable disease agents is a licensed product, Source Leukocytes, used in the manufacture of interferon, which requires rapid preparation from blood. Shipments of Source Leukocytes are pre-approved under a biologics license application and each shipment does not have to be reported to the agency. Based on information from CBER's database system, FDA receives less than 1 application per year from manufacturers of Source Leukocytes. However, for calculation purposes, we are estimating 1 application annually.

Under § 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D), FDA estimates that each manufacturer would ship an estimated 1 unit of human blood or blood component per month (12 per year) that would require two labels; one as reactive for the appropriate screening test under § 610.40(h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under § 610.40(h)(2)(ii)(D). According to CBER's database system, there are approximately 40 licensed manufacturers that ship known reactive human blood or blood components.

Based on information we received from industry, we estimate that approximately 18,000 donations: (1) annually test reactive by a screening test for syphilis, (2) are determined to be biological false positives by additional testing and (3) are labeled accordingly (§ 610.40(h)(2)(vi)).

Human blood or a blood component with a reactive screening test, as a component of a medical

device, is an integral part of the medical device, e.g., a positive control for an in vitro diagnostic testing kit. It is usual and customary business practice for manufacturers to include on the container label a warning statement that identifies the communicable disease agent. In addition, on the rare occasion when a human blood or blood component with a reactive screening test is the only component available for a medical device that does not require a reactive component, then a statement of warning is required to be affixed to the medical device. To account for this rare occasion under § 610.42(a), we estimate that the warning statement would be necessary no more than once a year.

FDA estimates that approximately 3,500 repeat donors will test reactive on a screening test for HIV. We also estimate that an average of three components was made from each donation. Under §§ 610.46(a)(1)(ii)(B) and 610.46(a)(3), this estimate results in 10,500 (3,500 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 10,500 (3,500 x 3) notifications to consignees of subsequent test results. We estimate an average of 10 minutes per notification of consignees.

Moreover, we estimate that § 610.46(b)(3) will require 4,980 consignees to notify transfusion recipients, their legal representatives, or physicians of record an average of 0.35 times per year resulting in a total number of 1,755 (585 confirmed positive repeat donors x 3) notifications. Under § 610.46(b)(3), we also estimate 1 hour to accommodate the time to gather test results and records for each recipient and to accommodate multiple attempts to contact the recipient.

Furthermore, we estimate that approximately 7,800 repeat donors per year would test reactive for antibody to HCV. Under §§ 610.47(a)(1)(ii)(B) and 610.47(a)(3), collecting establishments would notify the consignee 2 times for each of the 23,400 (7,800 x 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 46,800 notifications as an annual ongoing burden. Under § 610.47(b)(3), we estimate that approximately 4,980 consignees would notify approximately 2,050 recipients or their physicians of record annually. Finally, we estimate 1.0 hours to complete notification.

Industry estimates that approximately 13 percent of 10 million potential donors (1.3 million donors) who come to donate annually are determined not to be eligible for donation prior to collection because of failure to satisfy eligibility criteria. It is the usual and customary business practice of approximately 2,000 blood collecting establishments to notify onsite and to explain the reason why the donor is determined not to be suitable for donating. Based on such available information, we estimate that two-thirds (1,333) of the 2,000 blood collecting establishments provided on site additional information and counseling to a donor determined not to be eligible for donation as usual and customary business practice. Consequently, we estimate that only one-third, or 667, approximately, blood collection establishments would need to provide, under § 630.6(a), additional information and counseling to the estimated 430,000 (one-third of approximately 1.3 million) ineligible donors.

It is estimated that another 4.5 percent of 10 million donors (450,000 donors) are deferred annually based on test results. We estimate that currently approximately 95 percent of the establishments that collect 99 percent of the blood and blood components notify donors who

have reactive test results for HIV, Hepatitis B Virus (HBV), HCV, Human T-Lymphotropic Virus (HTLV), and syphilis as usual and customary business practice. Consequently, 5 percent of the 2,081 establishments (104) collecting 1 percent (4,500) of the deferred donors (450,000) would notify donor under § 630.6(a).

As part of usual and customary business practice, collecting establishments notify an autologous donor's referring physician of reactive test results obtained during the donation process required under § 630.6(d)(1). However, we estimate that approximately 5 percent of the 2,000 blood collection establishments (100) may not notify the referring physicians of the estimated 2 percent of 150,000 autologous donors with reactive test results (3,000) as their usual and customary business practice.

The recordkeeping chart reflects the estimate that approximately 95% of the recordkeepers, which collect 99% of the blood supply, have developed SOPs as part of their customary and usual business practice. Establishments may minimize burdens associated with CGMP and related regulations by using model standards developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

Under § 606.160(b)(1)(ix), we estimate the total annual records based on the 1.3 million donors determined not to be eligible to donate and each of the estimated 1.75 million (1.3 million + 450,000) donors deferred based on reactive test results for evidence of infection due to communicable disease agents. Under § 606.160(b)(1)(xi), only the 2,000 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 150,000 autologous donors (6,750) will be deferred under § 610.41 and thus result in the notification of their referring physicians.

FDA has concluded that the use of untested or incompletely tested but appropriately documented human blood or blood components in rare medical emergencies should not be prohibited. We estimate the recordkeeping under § 610.40(g)(1) to be minimal with one or less occurrence per year. The reporting of test results to the consignee in § 610.40(g) does not create a new burden for respondents because it is the usual and customary business practice or procedure to finish the testing and provide the results to the manufacturer responsible for labeling the blood products.

The hours per response and hours per record are based on estimates received from industry or FDA experience with similar recordkeeping or reporting requirements.

The development of labels is a one-time burden. The container labels have been standardized and are sold commercially. The label is only customized for the firm's name, address, and unique facility identifier. In addition, the instruction circular is updated as appropriate usually because of new industry information, is printed by major blood banking associations, and is sold at minimal cost to the firms. Therefore, no burden is imposed by FDA regarding the labeling and disclosure regulations (§§ 606.121 and 606.122).

Cost to Respondents

The estimated annual cost to respondents is $23,218,542.

Activity	**No. of Hours**	**Cost per Hour**	**Total Cost**
Reporting	67,547	$54	$3,647,538
Recordkeeping	362,426	$54	$19,571,004
Total			$23,218,542

The cost is based on a pay rate of $36/hour for a medical technologist (MT), 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 supervisor, at a pay rate of $48/hour 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 a Medical Director (MD), at a pay rate of $79/hour, 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 recordkeeping and reporting-disclosure requirements that are performed by the MT, supervisor, or MD, the cost/hour includes the average salary of the three ($54). These salary estimates include benefits but no overhead costs.

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

There are no capital or operating and maintenance costs associated with the collection of information.

14. Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government is $2,109,298. This estimate is based on a FDA reviewer or investigator at an average grade scale of GS-12/5 ($49/hour), who reviews the requests for approval submitted under §§ 610.40(g)(2) and 610.40(h)(2)(ii)(A), or performs biannual on-site inspections. The inspection cost includes inspection of a facility, review of facility records, and report preparation. The estimated cost is also based on a GS-13/5 ($59/hour) Consumer Safety Officer who compiles, reviews, and analyzes fatality reports. These salary estimates include benefits but no overhead costs.

Activity	Number of Respondents	Number of Hours	Cost per Hour	Total Cost
Product Release Review	2	1	$49	$98
Inspection	1,040	40	$49	$2,038,400
Fatality Report Review	100	12	$59	$70,800
Total				$2,109,298

15. Explanation for Program Changes or Adjustments

FDA is consolidating OMB control number 0910-0460 into 0910-0116. The previous estimated total annual burden was 564,678 hours for 0910-0116 and 495,309.5 hours for 0910-0460 (for a total of 1,059,987.5 hours). The current estimated total annual burden for 0910-0116 is 426,913 hours. The overall decrease in burden is 618,381 hours (1,059,987.5 - 426,913 = 633,074.5 hours) is mostly attributed to the revised estimate for the total annual records under § 606.160 (-150,000 hours) and the elimination of the one-time burden estimated in 0910-0460 (-456,280 hours). The decrease in burden for 0910-0116 is 137,765 hours (564,678 – 426,913 = 137,765 hours).

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 display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.