OMB INFORMATION COLLECTION
SUPPORTING STATEMENT
0910-0472

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents; and Requirements for Donor Notification

JUSTIFICATION

1. Circumstances Which Make This Information Collection Necessary

The Food and Drug Administration (FDA) is requesting an extension of Office of Management and Budget (OMB) Control No. 0910-0472, and OMB approval of the information collection requirements in 21 CFR Parts 606, 610, and 630 (Tab A) listed below:

21 CFR 610.40(c)(1)(ii)	Reporting	Requires each dedicated donation 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)(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.
21 CFR 610.40(h)(2)(ii)(A)	Reporting	Requires 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 a communicable disease agent(s) or collect 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 reactive human blood and blood components with the appropriate screening test results, and, if they are intended for further manufacturing use into injectable products, with a statement indicating the exempted use specifically approved by FDA.
21 CFR 610.40(h)(2)(vi)	Reporting	Requires each donation of human blood or blood component that tests reactive by a screening test for syphilis and is determined to be a biological false positive be labeled with both test results.
21 CFR 610.42(a)	Reporting	Requires a warning statement, including the identity of the communicable disease agent, on medical devices containing human blood or blood components found to be reactive by a screening test for evidence of infection due to a communicable disease agent(s) or syphilis.

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 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.
21 CFR 610.40(g)(1)	Recordkeeping	Requires an establishment to appropriately document a medical emergency for the release of human blood or blood components prior to completion of required testing.
21 CFR 606.160(b)(1)(ix)	Recordkeeping	Requires a facility 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.

Under sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264) (Attachment B) and the provisions of the Federal Food, Drug, and Cosmetic Act (the act) that apply to drugs (21 U.S.C. 321 et seq.) (Attachment C), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between States or Possessions or from foreign countries into the States or Possessions. The public health objective in testing human blood donors for evidence of infection due to communicable disease agents and in donor notification is to prevent the transmission of communicable disease. Section 351 of the PHS Act (42 U.S.C. 262(d)), applies to biological products. Blood and blood components are considered drugs, as that term is defined in section 201(g)(1) of the act (21 U.S.C. 321(g)(1)).

2. How, By Whom, and the Purpose for Collecting This Information

FDA recognizes that there are rare emergencies, i.e., where a patient's need for blood is so acute as to preclude any testing of the blood, that would afford the release for use prior to the completion of testing for markers of infection due to communicable disease agents. Upon FDA approval, collection facilities are permitted to ship under quarantine blood and blood components for further manufacturing before testing is completed to ensure the continued availability of biological products such as interferon, which requires rapid preparation from blood.

Blood establishments intending to distribute human blood or blood components for further manufacture or autologous use that are reactive for markers of infection with communicable disease agents are required to apply for approval by FDA. The written application would describe the intended use of the blood or blood component, including identification of all consignees and the procedures for collecting, handling, labeling, and shipping the blood.

The disclosure requirements ensure that personnel handling human blood or blood components that have tested repeatedly reactive for markers of infection with communicable disease agents are aware of this fact and can take appropriate safety precautions.

The donor notification process is intended to prevent further donations from donors who have been deferred for positive test results for markers of 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. Since autologous donors donate blood or blood components for their own use per prescription by their physician, reactive test results for a communicable disease agent on an autologous donor are sent to the referring physician. Awareness of reactive test results will aid the referring physician in the treatment and counseling of the autologous donor.

3. Use of Technology to Reduce the Burden on the Public

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 other improved technology to reduce the burden except that unautomated blood establishments could reduce the time required to maintain records with respect to input and retrieval by becoming computerized.

4. Identification and Use of Duplicate Information

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

5. FDA's Effort to Reduce Burden on Small Businesses

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. The Center for Biologics Evaluation and Research (CBER), Office of Communication, Training, and Manufacturer's Assistance provides assistance to small businesses subject to FDA's regulatory requirements.

6. Impact of Not Collecting This Information or Collecting Information Less Frequently

Less frequent collection of information or other methods of reducing the frequency of information would not provide the information needed to prevent the transmission of communicable disease by blood and blood components. There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances That Occur When Collecting This Information

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

8. Identification of Outside FDA Sources

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice in the **Federal Register** on March 16, 2004 (69 FR 12334, Tab D), for public comment on the information collection provisions. We received one comment from the industry on the proposed information collection. The commenter stated that they had no reason to believe FDA's burden estimates were not reasonable. Also, the commenter did not believe the estimated times constituted a burden on community blood centers.

9. Payment or Gifts Offered to Respondents

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

10. Method of Ensuring Respondent Confidentiality

The confidentiality of information received by FDA would be consistent with the Freedom of Information Act and the agency's regulations under 21 CFR Part 20. 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. Use of Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Burden Hour and Costs Associated With This Information Collection

The estimated annual burden for this information collection is 145,270 hours.

Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
610.40(c)(1)(ii)	942	13	12,000	.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 (D)	40	12	480	0.2	96
610.40(h)(2)(vi)	942	19	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
630.6(a)[1]	311	1,393	433,333	0.08	34,667
630.6(a)[2]	47	191	9,000	1.5	13,500

630.6(d)(1)	43	140	6,000	1	6,000
Total					56,666

[1]Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[2]Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
610.40(g)(1)	858	1	858	0.5	429
606.160(b)(1)(ix)	942	1,858	1,750,000	0.05	87,500
606.160(b)(1)(xi)	858	16	13,500	0.05	675
Total					88,604

Respondents to this collection of information are Whole Blood and Source Plasma establishments that collect blood and blood components, including Source Plasma and Source Leukocytes. Based on information from FDA's CBER database system, there are approximately 84 licensed Source Plasma collection establishments and 858 registered Whole Blood collection establishments for a total of 942 establishments. Based on information received from industry, we estimate that these establishments collect annually an estimated 30 million donations: 15 million donations of Source Plasma from approximately 2 million donors and 15 million donations of Whole Blood, including 600,000 autologous, from approximately 8 million donors.

Assuming each autologous donor makes an average of 2 donations, FDA estimates that there are approximately 300,000 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 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 an estimated 1 application per year from manufacturers of Source Leukocytes.

Under §§ 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D), FDA estimates that each manufacturer would ship an estimated 1 human blood or blood components per month (12 per year) that would require two labels; one as reactive for the appropriate screening test under paragraph (h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under paragraph (h)(2)(ii)(D). According to CBER's database system, there are an estimated 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 annually test reactive by a screening test for syphilis, and are determined to be biological false positives by additional testing (§ 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.

Industry estimates that approximately 13 percent of 10 million 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 virtually all 942 collecting establishments to notify on site and to explain the reason why the donor is determined not to be eligible for donating. Based on such information as is available to FDA, we estimate that two-thirds of the 942 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 311 collection establishments would need to provide, under § 630.6(a), additional information and counseling on site to 433,333 (1/3 of 1.3 millions) 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 95 percent of the establishments that collect 98 percent of the blood and blood components notify donors who have reactive test results for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-Lymphotropic virus (HTLV), and syphilis as usual and customary business practice. Consequently, 5 percent (47) of the industry (942) collecting 2 percent (9,000) of the deferred donors (450,000) would experience burden related to § 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 5 percent of the 858 blood collection establishments (43) do not notify the referring physicians of the estimated 2 percent of 300,000 autologous donors with reactive test results (6,000).

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.

Section 606.160(b)(1)(ix) requires that establishment to maintain records of the notification efforts. We estimate the total annual records based on the 1.3 million donors determined not to be eligible to donate and each of the 450,000 (1.3+450,000=1,750,000) donors deferred based on reactive test results for evidence of infection due to communicable disease agents. Under §

606.160(b)(1)(xi), only the 858 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 300,000 autologous donors (13,500) will be deferred under § 610.41 and thus result in the notification of their referring physicians.

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

Cost to Respondents

The estimated annual cost to respondents is $4,350,890.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	56,666	$33	$1,869,978
Recordkeeping	88,604	$28	$2,480,912

The cost estimate is based on a medical technologist or supervisor, at an estimated average wage of $ 33 ($(28+38)/2) per hour, who is responsible for the reporting activities and a medical technologist, at an estimated average hourly wage of $28, who is responsible for the recordkeeping activities. This salary estimate includes benefits but no overhead costs.

13. Annual Cost Estimate to Respondents

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

14. Annual Cost Estimate to FDA

The estimated annual cost to the Federal Government is $697,154. The cost estimate is based on an FDA reviewer or investigator at an average grade of GS-12/5 ($37/hour), who takes an average of 1 hour to review the requests for approval submitted under §§ 610.40(g)(2) and 610.40(h)(2)(ii)(A). This estimate is also based on an FDA investigator at an average grade of GS-12/5 ($37/hour) who performs biannual on-site inspections. This cost includes inspection of a facility, review of facility records, and report preparation.

Activity	Number of Respondents	Number of Hours	Cost per Hour	Total Cost
Review	2	1	$37	$74
Inspection	471	40	$37	$697,080

15. Changes from Previous Approval

FDA is consolidating the OMB Control No. 0910-0474 into 0910-0472. The previous burden estimate under 0910-0474 was 141,681 hours, and under 0910-0472 was 3,125 hours (combined

total of 144,806 hours). The increase in burden in the current package (0910-0472) to 145,270 hours is due to the consolidation of packages. The overall increase from the previous burden estimate of 144,806 hours to the current burden estimate of 145,270 hours is negligible.

16. Publishing the Results of This Information Collection

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

17. Reason for Not Displaying the OMB Approval Date

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

18. Explanations to Section 19, "Certification for Paperwork Reduction Act Submissions"

There are no exceptions to Item 19 of OMB Form 83-I.