OMB INFORMATION COLLECTION
SUPPORTING STATEMENT

Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback); Final Rule
0910-0460

A. JUSTIFICATION

1. Need and Legal Basis

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information collection requirements contained in the final rule amending 21 CFR Part 606 and 21 CFR Part 610. These requirements are listed below.

606.100(b)(19)	Recordkeeping	Requires collecting establishments and consignees to prepare and follow written procedures for "lookback" when a donor who tests reactive for evidence of human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection either on a repeat donation or after a review of historical testing records.
606.160(b)(1)(viii)	Recordkeeping	Requires records concerning the following activities performed under §§ 610.46, 610.47, 610.48: quarantine; consignee notification; testing; notification of a transfusion recipient, the recipient's physician of record, or legal representative; and disposition.
610.46(a)(1)(ii)(B) 610.47(a)(1)(ii)(B) 610.48(b)(3)(ii) and (iii)	Reporting	Requires collecting establishments to notify consignees to quarantine previously collected in-date blood and blood components, and of further test results if available.
610.46(a)(3) 610.47(a)(3) 610.48(b)(4)	Reporting	Requires notification of consignees of further testing results.
610.46(b)(3) 610.47(b)(3) 610.48(c)(3)	Reporting	Requires consignees to notify transfusion recipients, physicians of record, or legal representatives that the recipient received blood and blood components at increased risk of transmitting HIV or HCV.

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 et seq.) and the provisions of the Federal Food, Drug, and Cosmetic Act (the act), which apply to drugs (21 U.S.C. 201 et seq.) 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.

FDA is taking this action to help ensure the continued safety of the blood supply and to help ensure that information is provided to recipients of blood and blood components that may have been at increased risk of transmitting HIV or HCV infection.

The existing requirements for HIV "lookback" are revised to be consistent with the requirements for HCV "lookback."

2. Information Users

Collecting establishments must review previous testing records of a donor who tests reactive for evidence of human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection either on a repeat donation or after a review of historical testing records. The review of records is to identify previously donated blood and blood components that may be at risk of transmitting HIV or HCV infection to a recipient. The purpose of the final rule is to help ensure the continued safety of the blood supply. This collection of information provides important information to consignees and/or recipients of prior collections of blood and blood components, including Source Plasma and Source Leukocytes, from a donor who later returned to donate and tested repeatedly reactive for antibody to HIV or HCV. This makes it possible for consignees to quarantine such prior collections that remain in inventory and that may be at increased risk for transmitting HIV or HCV. It also provides the opportunity for recipients of such prior collections to be informed of the need for HIV or HCV testing and medical counseling.

The information collection for HIV "lookback" is currently approved under OMB No. 0910-0116. The information for HCV "lookback" is a new collection.

3. Improved Information Technology

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. Duplication 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. 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, 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. Less Frequent Collection

Section 610.48 requires the review of historical testing records to identify previously donated blood and blood components by a donor who has a subsequent historical test reactive for evidence of HCV infection only. This retrospective review is a one-time burden.

Sections 610.46 and 610.47 requires an on-going review of previously donated blood and blood components when a donor has previously tested nonreactive for evidence of HIV or HCV infection, respectively, and then donates again and tests reactive for evidence of HIV or HCV infection.

The collection of information occurs only as needed, at the time when a donor returns to donate and tests repeatedly reactive for evidence of HIV or HCV infection. Less frequent collection of information and notification of consignees and transfusion recipients would not ensure the safety of the nation's blood supply. The information provided to consignees and transfusion recipients is necessary to fulfill FDA's statutory responsibility to prevent the spread of communicable diseases. FDA would be unable to fulfill these duties with less frequent information collection.

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

7. Special Circumstances

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

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), we provided an opportunity for public comment on the information collection requirements of the proposed rule (65 FR at 69402). FDA invited 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.

No comments on the information collection requirements were submitted to OMB or the docket.

9. Payment/Gift to Respondent

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

10. Confidentiality

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 deleted before the report would be released under the Freedom of Information Act and applicable FDA regulations.

11. Sensitive Questions

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

12. Burden Estimate (Total Hours and Wages)

The total reporting and recordkeeping burden for the first year is estimated to be 495,309.5 hours. However, of this total approximately 456,280 hours would be expended on a one-time basis for establishing the written procedures and doing the one-time retrospective review of historical HCV testing records. Therefore, 39,029.5 hours is estimated as the ongoing annual burden related to these regulations. The total ongoing annual burden for collecting establishments under §§ 610.46(a)(1)(ii)(B), 610.46(a)(3), 610.46(b)(3), and 606.160(b)(1)(viii) for HIV "lookback" is estimated to be 12,763 hours. The total ongoing annual burden for collecting establishments under §§ 610.47(a)(1)(ii)(B), 610.47(a)(3), 610.47(b)(3), and 606.160(b)(1)(viii) for HCV "lookback" is estimated to be 26,266.5 hours. When an estimate was not available for the annual frequency of either responses or records, we divided the estimated total annual responses or records with the applicable number of respondents or recordkeepers. Total hours are calculated by multiplying the total annual responses or records by the hours spent per

response or record.

Table1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.46(a)(1)(ii)(B)	981	10.7	10,500	0.17	1,785
610.46(a)(3)	981	10.7	10,500	0.17	1,785
610.46(b)(3)	4,980	0.35	1,755	1.0	1,755
610.47(a)(1)(ii)(B)	981	23.85	23,400	0.17	3,978
610.47(a)(3)	981	23.85	23,400	0.17	3,978
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
Total					15,331

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

Table 2.--Estimated One-Time Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.48(b)(3)(ii) and (b)(3)(iii)	981	216.1	212,000	0.17	36,040
610.48(b)(4)	981	216.1	212,000	0.17	36,040
610.48(c)(3)	4,980	42.57	212,000	1.0	212,000
Total					284,080

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

Table 3.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.160(b)(1)(viii)					
HIV consignee notification	981	21.4	21,000	.17	3,570
	4,980	4.2	21,000	.17	3,570
HCV consignee notification	981	47.71	46,800	.17	7,956
	4,980	9.4	46,800	.17	7,956
HIV recipient notification	4,980	0.35	1,755	.17	298
HCV recipient notification	4,980	0.41	2,050	.17	348.5
Total					23,698.5

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

Table 4.--Estimated One-Time Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b)(19)	1,041	1	1,041	40	41,640
606.100(b)(19)	4,980	1	4,980	16	79,680
606.160(b)(1)(viii)	1,041	203.65	212,000	.08	16,960
606.160(b)(1)(viii)	4,980	42.57	212,000	.08	16,960
610.48(c)(3)	4,980	42.57	212,000	.08	16,960
Total					172,200

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

Based on information retrieved from FDA's registration data base, there are approximately 1,041 FDA registered establishments (60 licensed plasma establishments and 981 registered collecting establishments) in the United States that collect approximately 27 million allogeneic donations annually: 13 million donations of Source Plasma and 14 million donations of Whole Blood, including 695,000 autologous units. There are approximately 11.2 million donations from repeat donors per year (14 million donations x 80 percent of donations from repeat donors). The Source Plasma industry will only be minimally affected by these requirements. Therefore, we are only estimating burden for Source Plasma collecting establishments in regards to § 606.100(b)(19). The following reporting and recordkeeping estimates are based on information provided by industry and FDA experience.

Annual Reporting Burden (Table 1)

1. HIV Reporting Burden

In table 1, we estimate that approximately 3,500 repeat donors will test reactive on a screening test for HIV. We estimate that an average of three components were made from a previously collected 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. The estimate for consignee notifications in the final rule is higher than the estimate in the proposed rule because we based our calculations in the final rule on the number of components at risk of transmitting HCV infection rather than the number of reactive donors. We also have increased the number of components per donation from two to three.

In addition, we estimate that § 610.46(b)(3) will require 4,980 consignees to notify transfusion recipients 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. In the proposed rule, we estimated 0.5 hours as the average time for a reasonable attempt to notify recipients by consignees. However, under § 610.46(b)(3), we are increasing the estimate to one hour to accommodate the time to gather test results and the recipient's records and to accommodate multiple attempts to contact the recipient.

2. HCV Reporting Burden (Table 1)

We estimate that approximately 7,800 repeat donors per year would test reactive for antibody to HCV (780 repeat donors confirmed HCV positive / 0.1 rate for repeat donors confirmed HCV positive / repeat donors with reactive tests = 7,800 repeat donors with reactive tests). Under §§ 610.47(a)(1)(ii)(B) and 610.47(a)(3), collecting establishments would notify the consignee two 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 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 (780 HCV positive donors x 3.1 components per donor x 85 percent transfused) or their physicians of record annually. The estimated average 1.0 hour to complete notification is based on the criteria discussed in the previous section on HIV Reporting Burden.

Estimated One-Time Reporting Burden (Table 2)

Based on estimates from CDC, we expect that for the one-time retrospective review of historical testing records, as many as 212,000 blood components (188,448 components + [115,228 components x 20 percent]) would be at increased risk for transmitting HCV. For each of these products, under §§ 610.48(b)(3)(ii) and (iii), and 610.48(b)(4) collecting establishments must notify consignees to quarantine these products and report additional HCV test results to consignees, and, under § 610.48(c)(3), consignees must notify transfusion recipients or recipients' physicians of record. CDC estimated that there could be approximately 212,000 transfusion recipients that would be notified after a one-time retrospective review of historical test results for HCV screening. The numbers in the hours per response column are the same as the burden for table 1.

Estimated Annual and One-Time Recordkeeping Burden (Table 3 and Table 4)

In the recordkeeping tables, the numbers in the hours per record column are based on our estimate of the time to complete one record. We also estimate that each documentation of consignee and recipient notification takes approximately 5 minutes. In table 4, we estimate that it will take collecting establishments approximately 40 hours to establish the written procedures required under § 606.100(b)(19) and consignees approximately 16 hours to establish written procedures under § 606.100(b)(19). In table 3, the estimate for annual recordkeeping is based on the estimate that it takes approximately 10 minutes to document and maintain the records to relate the donor with the unit number of each previous donation for both the collecting establishment and the consignee. The time required for recordkeeping under § 606.160(b)(1)(viii) is estimated to be approximately 10 minutes for each HIV or HCV reactive donation record and approximately 10 minutes per transfusion recipient record required under §§ 610.46 (b)(3), 610.47(b)(3) and 610.48(c)(3).

Because the final rule will not affect current industry practice of retaining "lookback" records for 10 years, no burden is calculated for § 606.160(d).

Cost to Respondents

Table 5 - Costs to Respondents

Activity	No. Of Hours	Cost per Hour	Total Cost
Reporting (One-time burden)	284,080	$31	$8,806,480
Recordkeeping (One-time burden)	172,200	$31	$5,338,200
Total	456,280		$14,144,680
Reporting (Annual burden)	15,331	$31	$475,261
Recordkeeping (Annual burden)	23,698.5	$31	$734,653.50
Total	39,029.5		$1,209,914.50

The total cost to the respondents the first year is estimated at approximately $15,354,595 based on the following information. An establishment's medical technologist, at $31 per hour, will expend approximately 495,309.5 hours on reporting and recordkeeping responsibilities. After the first year, the costs will not include those for establishing written procedures and performing the retrospective "lookback" (one-time burden), i.e., 456,280 hours. Therefore, 39,029.5 hours is estimated as the ongoing annual burden related to these regulations ($1,209,914.5). The salary estimate includes benefits but no overhead cost.

13. Capital Costs (Maintenance of Capital Costs)

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

14. 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. Program or Burden Changes

This burden represents a new collection of information. FDA is issuing this final rule to help ensure the continued safety of the blood supply and to help ensure that information

is provided to recipients of blood and blood components that may have been at increased risk of transmitting HIV or HCV infection.

16. Publication and Tabulation Dates

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

17. Display of OMB Approval Date

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 Item 19 of OMB Form 83-I.

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Drafted: McKeever 8/31/04
Reviewed: Swisher 9/2/04
Revised per edits from Swisher 9/29/04