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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2250]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *(insert date 30 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection—21 CFR 606.100, 606.160, 610.46, and 610.47 (OMB Control No. 0910–0336)—
Extension**

Under the biologics licensing and quarantine provisions of the Public Health Service Act (42 U.S.C. 262–264) and the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351–353, 355–360, and 371–374), FDA has the authority to issue regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. FDA has implemented an extensive system of donor screening and testing procedures performed by blood establishments before, during, and after donation, to help prevent the transfusion of blood products that are at increased risk for transmitting human immunodeficiency virus (HIV). HIV is the virus that causes acquired immune deficiency syndrome (AIDS), a communicable disease that can be transmitted through transfusion. Despite the best practices of blood establishments, however, a person may donate blood early in infection, during the period when the antibody to HIV is not detectable by a screening test, but HIV is present in the donor's blood (a so-called "window" period). If the donor attempts to donate blood at a later date, the test for antibody to HIV may, at that time, be repeatedly reactive. Therefore, FDA believes such circumstances require clarification of the donor's status through testing with a more specific antibody test and procedures to "lookback" at prior collections.

FDA issued regulations that require blood establishments to follow written standard operating procedures (SOP's) when the blood establishments have collected Whole Blood, blood components, Source Plasma, and Source Leukocytes later determined to be at increased risk for transmitting HIV. When a donor who previously donated blood is tested on a later donation, and tests repeatedly reactive for antibody to HIV, the regulations require blood establishments to perform more specific testing using a licensed test, and notify consignees who received Whole Blood, blood components,

Source Plasma, and Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collection Whole Blood, blood components, Source Plasma, and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients. Upon completion of more specific testing, hospital transfusion services that do not participate in Medicare, and are therefore not subject to Health Care Financing Administration's (HCFA's) regulations, are required to take steps to notify transfusion recipients, as appropriate. These regulations are intended to help ensure the continued safety of the blood supply by providing necessary information is provided to users of blood and blood components and appropriate notification of recipients of transfusion at increased risk for transmitting HIV infection.

Section 606.100(b)(19) (21 CFR 606.100(b)(19)) requires written SOP's for the following procedures: (1) Review prior donations of blood and blood products from donors with no previous history of antibody to HIV who subsequently test repeatedly reactive for the antibody to HIV; (2) quarantine in-house blood and blood products; (3) notify consignees regarding the need to quarantine such products; (4) determine the suitability for release of such products from quarantine; (5) notify consignees of such products with antibody testing results from "lookback" donors; and (6) notify attending physicians so that transfusion recipients are informed that they may have received blood and blood components at increased risk for transmitting HIV. Section 606.160(b)(1)(vii) (21 CFR 606.160(b)(1)(vii)) requires records to relate the donor with the unit number of each previous donation from that donor. Section 606.160(b)(1)(viii) requires records of quarantine, notification, testing, and disposition performed under §§ 610.46 and 610.47 (21 CFR 610.46 and 610.47). Section 610.46(a) requires blood establishments to notify consignees, within 72 hours, of repeatedly reactive tests results so that previously collected blood and blood components are appropriately quarantined. Section 610.46(b) requires blood establishments to notify consignees of licensed, more specific test results for HIV within 30-calendar days after the donors's repeatedly reactive test. Section 610.47(b) requires transfusion services not subject to HCFA

regulations to notify physicians of prior donation recipients or to notify recipients themselves of the need for HIV testing and counseling. There are approximately 3,076 registered blood establishments that annually collect an estimated 24 million units of Whole Blood and Source Plasma, and that are required to follow FDA “lookback” procedures. Of these establishments, approximately 180 are registered transfusion services that are not subject to HCFA’s “lookback” regulations.

The following reporting and recordkeeping estimates are based on information provided by industry, and FDA experience. In Table 1 of this document, it is estimated that an average of 60 repeat donors per establishment will test repeatedly reactive annually. This estimate results in a total number of 184,560 notifications of these test results to consignees by blood establishments for the purpose of quarantine of affected products, and another 184,560 notifications to consignees of subsequent test results. It is estimated that transfusion services not subject to HCFA’s regulations will need to notify physicians, or in some cases recipients, an average of 16 times per year resulting in a total number of 2,880 notifications. FDA estimates an average of 10 minutes per notification of consignees, physicians, and recipients. The estimate of one-half hour for § 610.47(b) is based on the minimum requirement of three attempts to notify recipients by transfusion services. In Table 2 of this document, the estimate of 154 recordkeepers and 160 records is based on the estimate that the requirement is already implemented voluntarily by more than 95 percent of the facilities, which collect 98 percent of the Nation’s blood supply. FDA estimates that it takes approximately 5 minutes to document and maintain the records to relate the donor with the unit number of each previous donation. The establishment of SOP’s under § 606.100(b)(19) is a one-time burden. The maintenance of the SOP’s is considered usual and customary business practice, therefore no burden is calculated for the preparation and updating of the SOP.

In the **Federal Register** of August 3, 1999 (64 FR 42132), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—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)	3,076	60	184,560	0.17	31,375
610.46(b)	3,076	60	184,560	0.17	31,375
610.47(b)	180	16	2,880	0.5	1,440
Total					64,190

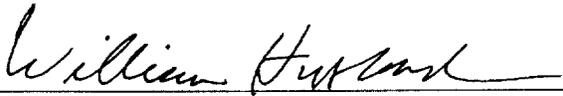
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.160(b)(1)(vii)	154	160	24,640	12.8	1,971
606.160(b)(1)(viii)	3,076	60	184,560	4.8	14,765
Total					16,736

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

Dated: October 27, 1999



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

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