1996 (61 FR 37357) remains August 19, 1996. Effective September 9, 1996, the compliance date with respect to these amendments to Form BD is suspended. The Commission will publish in the Federal Register a document notifying the public of a new compliance date.

FOR FURTHER INFORMATION CONTACT: Glenn J. Jessee, Special Counsel, (202) 942–0073, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Mail Stop 5–10, Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION: On July 12, 1996, the Securities and Exchange Commission (''Commission'') adopted amendments to Form BD,[1] the uniform application form for broker-dealer registration under the Securities Exchange Act of 1934.[2] As discussed in the Adopting Release, the use of Form BD, as amended on July 12, 1996, is intended to coincide with the implementation of the redesigned Central Registration Depository (''CRD''), a computer system operated by the National Association of Securities Dealers, Inc. (''NASD'') that maintains registration information regarding broker-dealers and their registered personnel. Among other things, the redesigned CRD system will allow broker-dealers to file Form BD electronically.

The implementation of the redesigned CRD is being accomplished in phases. On May 20, 1996, the NASD began a two-month test of the system with the voluntary participation of several NASD member firms and one service bureau. Following completion of the test, it was expected that on July 29, 1996, broker-dealers participating in the test would begin filing all of their registration and licensing information electronically with the redesigned CRD on a pilot basis. Then, on September 9, 1996, it was expected that the NASD would begin Phase I of the implementation of the redesigned CRD system, at which time registered broker-dealers and broker-dealer applicants would be required to begin using Form BD, as amended on July 12, 1996. The test of the redesigned CRD system that began on May 20, however, revealed that additional changes are needed in the software that will be used by broker-dealers to make electronic filings and that broker-dealers need more time to prepare their internal operations and infrastructure to support electronic filing. As a result, the NASD has determined to delay further implementation of the redesigned CRD system until early in 1997.

Because of this delay, the Commission is suspending the compliance date for Form BD, as amended on July 12, 1996, for all registered broker-dealers and broker-dealer applicants. Accordingly, broker-dealers and broker-dealer applicants should continue to use Form BD, as revised November 16, 1992. At such time as another date for the start of Phase I is determined, the Commission expects that it will set appropriate compliance dates for the amendments to Form BD and publish a document in the Federal Register notifying the public of such compliance dates.

Dated: September 4, 1996.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 96–22939 Filed 9–6–96; 8:45 am]

BILLING CODE 8010–01–P

[1] 17 CFR 240.15b1–1; 17 CFR 249.501.

[2] Securities Exchange Act Release No. 37431 (Jul. 12, 1996), 61 FR 37357 (Jul. 18, 1996) (''Adopting Release'').

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 610

[Docket No. 91N–0152]

RIN 0910–AA05

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to require that blood establishments (including plasma establishments) prepare and follow written procedures for appropriate action when it is determined that Whole Blood, blood components (including recovered plasma), Source Plasma and Source Leukocytes at increased risk for transmitting human immunodeficiency virus (HIV) infection have been collected. This final rule requires that when a donor who previously donated blood is tested on a later donation in accordance with the regulations, and tests repeatedly reactive for antibody to HIV, the blood establishment shall perform more specific testing using a licensed test, if available, and notify consignees who received Whole Blood, blood components, Source Plasma or Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients.

The Health Care Financing Administration (HCFA) is also issuing a final rule, published elsewhere in this Federal Register, which requires all transfusion services subject to HCFA's conditions of Medicare participation for hospitals to notify transfusion recipients who have received Whole Blood or blood components from a donor whose subsequent donation test results are positive for antibody to HIV (hereinafter referred to as HCFA's final rule). FDA is requiring transfusion services that do not participate in Medicare and are, therefore, not subject to HCFA's final rule, to take steps to notify transfusion recipients.

FDA is taking this action to help ensure the continued safety of the blood supply, and to help ensure that information is provided to consignees of Whole Blood, blood components, Source Plasma and Source Leukocytes and to recipients of Whole Blood and blood components from a donor whose subsequent donation tests positive for antibody to HIV.

DATES: This regulation is effective November 8, 1996. Written comments on the information colelction requirements should be submitted by February 7, 1997.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

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 HIV. HIV is the virus that causes acquired immune deficiency syndrome (AIDS), a

communicable disease that can be transmitted through transfusion.

As a result of the screening and testing procedures, the risk of transmitting HIV infection through blood transfusion is very low. 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. Previously collected Whole Blood and blood components would be at increased risk for transmitting HIV and a recipient of a transfusion of Whole Blood and blood components collected during the ''window'' period would not know that he or she may have become infected with HIV through the transfusion unless notified.

In the Federal Register of June 30, 1993 (58 FR 34962), FDA issued a proposed rule to require appropriate action when it is later determined that blood and blood components might have been collected during the ''window'' period. FDA has reviewed comments submitted on the proposed rule and is now issuing this final rule to require facilities involved in the collection, processing, and administration of blood to quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes which were collected from a donor who tested negative at the time of previous donations but subsequently tests repeatedly reactive for antibody to HIV. The final rule requires blood establishments to inform consignees (e.g., hospital transfusion services and manufacturers of plasma derivatives) of the collection and distribution of such previously donated Whole Blood, blood components, Source Plasma and Source Leukocytes.

In the Federal Register of June 30, 1993 (58 FR 34977), HCFA also issued a proposed rule which would require certain transfusion services to notify recipients of transfusions determined to be from a donor whose subsequent donation tests positive for antibody to HIV (hereinafter referred to as HCFA's proposed rule). The final rules issued by both FDA and HCFA require transfusion services to perform such notifications.

In a memorandum of understanding (MOU), FDA and HCFA agreed to coordinate the inspections of transfusion services in medicare participating hospitals to minimize duplication of effort and to reduce the burden on affected facilities. Blood establishments, including those hospital transfusion services not subject to HCFA's regulations on the conditions of Medicare participation for hospitals, such as Indian Health Service and Veteran's Administration Hospitals, are subject to FDA's final rule. Thus, all transfusion services are subject to the requirements for quarantine and transfusion recipient notification under either the FDA or HCFA rule.

II. Highlights of the Final Rule

Under the biologics licensing and quarantine provisions of the Public Health Service Act (42 U.S.C. 262–264) and the drug, device, and the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351–353, 355–360, and 371–374), FDA has the authority to promulgate regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the transmission of communicable diseases into the United States or from one State to another.

Under these statutory authorities, FDA currently requires that each donation be tested and found negative for antibody to HIV under § 610.45 (21 CFR 610.45). Existing regulations already restrict the use, for transfusion or further manufacture, of a donation testing repeatedly reactive for antibody to HIV. Even though current licensed screening tests for antibody to HIV are very sensitive, testing may not identify all units capable of transmitting HIV infection. For this reason, many blood establishments have instituted special procedures when blood or plasma has been collected from a donor testing positive for antibody to HIV at a later date. These procedures, commonly referred to as ''lookback'' procedures, involve determining the suitability of prior collections of Whole Blood, blood components, Source Plasma and Source Leukocytes from such a donor. These existing procedures may also involve notifying consignees that have received prior collections from the donor so consignees can quarantine such products and, as appropriate, take steps to notify the transfusion recipients of such Whole Blood and blood components.

While many blood establishments have voluntarily developed written ''lookback'' procedures, these existing procedures vary significantly among blood establishments. As proposed in the Federal Register of June 30, 1993, FDA is amending the biologics regulations to require blood establishments to prepare and follow written standard operating procedures (SOP's), defining steps to be taken when ''lookback'' circumstances arise.

The final rule requires blood establishments to perform more specific testing of the donor's blood using a licensed test, and to 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 shall quarantine, as described later in this document, previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors until the donor's status is clarified through further testing. FDA is requiring that other informative test results, if available, be considered when determining the status of the donor and the suitability of prior collections.

Upon completion of more specific testing, the final rule also requires hospital transfusion services that do not participate in Medicare and are, therefore, not subject to HCFA's final rule, to take steps to notify transfusion recipients, as appropriate. Such transfusion recipients shall receive notification for the purpose of testing for evidence of HIV infection, early treatment, if indicated, and counseling to take appropriate precautions to prevent the further spread of the virus such as to sexual partners.

III. HCFA's Companion Rule

Under HCFA's proposed rule, transfusion services operated by hospitals participating in Medicare and inspected by HCFA that receive notification of previously collected Whole Blood and blood components at increased risk for transmitting HIV, would be required to quarantine such prior collections and notify the transfusion recipient's attending physician, the transfusion recipient, or other authorized person, as appropriate. HCFA's final rule requires the hospital transfusion service to have a written agreement with each blood supplier documenting these procedures.

As referenced in section I. of this document, FDA and HCFA coordinate the inspections of transfusion services in medicare participating hospitals to minimize duplication of effort and to reduce the burden on affected facilities. In the MOU, it was estimated that HCFA would be responsible for inspecting and surveying approximately 3,000 transfusion services. FDA continues to conduct the inspections of

establishments were activities include more than the performance of compatibility testing. (See 49 FR 34448, August 31, 1984, and 21 CFR 607.65.)

IV. Other Sources of Information

As FDA recognized in the preamble to the proposed rule, blood establishments may receive information from other sources which indicate that a donor may be infected with HIV. FDA encourages blood establishments to initiate ''lookback'' procedures whenever they have information that a donor has become infected with HIV. FDA recognizes the existence of diagnostic modalities for HIV infection, other than antibody testing, such as virus culture or direct viral assays. FDA encourages blood establishments to consider such test results, when available and reliable, and to voluntarily initiate the ''lookback'' process as described in this final rule. Additionally, the final rule requires that such results be considered prior to release of units quarantined in a ''lookback'' procedure.

In particular, FDA recommends that blood establishments voluntarily initiate ''lookback'' procedures based on HIV antigen testing, as indicated in the August 8, 1995, Memorandum to All Registered Blood Establishments, Regarding Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen. In the August 8, 1995, memorandum FDA provided recommendations for the implementation of donor screening tests for HIV type 1 (HIV–1) antigen(s) within 3 months of the commercial availability of the first test for HIV–1 antigen(s). The August 8, 1995, memorandum stated that the average infectious ''window'' period, when HIV antibody is not detectable by the screening test, is estimated to be approximately 22 to 25 days for screening with combination assays for antibodies to HIV–1 and HIV–2. The memorandum further stated that HIV antigen screening could reduce the ''window'' period by an estimated 6 days and could be expected to prevent up to 25 percent of the current ''window'' period donations or about 5 to 10 cases of transfusion associated HIV per year. Because HIV–1 antigen screening will reduce but not eliminate the residual risk for HIV–1 from transfusion, FDA regards such screening as an interim measure pending the availability of improved technology for this purpose. FDA encourages continued development of new methods no further reduce the risk of HIV transmission due to ''window'' period donations.

V. Responses to Letters of Comment

FDA provided interested individuals 60 days to submit written comments on the proposed rule. FDA received a total of 25 letters of comment, which included 10 from blood collection facilities or blood banks, 8 from pathologists or pathology associations, 6 from blood banking associations, and 1 from a parent of children with hemophilia.

Twenty-one comments agreed with the concept of ''lookback''. There were differences of opinion as to how the ''lookback'' process should be conducted and concerns regarding liability of various individuals involved in the process. Three comments indicated support for the strengthening of the ''lookback'' requirements, while eight comments suggested that the proposed rule's cost to industry would pose a significant burden with little benefit to public health.

After review and consideration of all comments, FDA continues to believe that the new requirements for the handling of prior collections of Whole Blood, blood components, Source Plasma and Source Leukocytes later found to be at increased risk for transmitting HIV infection are important public health measures. Below, FDA provides responses to the comments received.

A. General Comments

1. Terminology Used by FDA and HCFA

Two comments expressed some confusion over specific terminology and the differences in terminology used by FDA and HCFA. One comment suggested the use of ''transfusion service'' instead of ''consignee.'' One comment suggested the use of a more specific term for ''recipient.''

FDA's use of the term consignee includes any facility to which the Whole Blood, blood components, Source Plasma and Source Leukocytes have been shipped (e.g., a transfusion service, a manufacturer of blood products, or another blood banking establishment). As written, when the rule uses the term consignee, it refers to more than a transfusion service. The FDA and HCFA rules refer to ''transfusion services'' when the rules are specific to transfusion services. To interchange these terms would cause more confusion and would not achieve the goals sought.

As suggested by one comment, FDA has amended the rule to use the terms transfusion recipient or transfused patient in a number of places to make it clear that FDA is referring to the recipient of the transfusion. Where the term ''recipient'' is used alone, FDA believes that the context makes it clear that the term refers to patients and not to consignees.

FDA believes that the terminology used in the rules is appropriate and understood by the entities subject to FDA regulation. FDA also believes that the terminology used by HCFA is understood by the entities regulated by HCFA.

2. Blood Donor Locator Service

Three comments stated an interest in using the Blood Donor Locator Service (BDLS) as a part of the ''lookback'' process. One request was to expand this service to locate recipients also.

The BDLS final rule which was published in the Federal Register of December 24, 1991 (56 FR 66561), addressed similar comments calling for the expanded use of the service. The statutory authority to conduct the BDLS, as defined by section 8008 of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100–647), only authorizes the Social Security Administration to provide address information for blood donors whose test results for antibody to HIV show that they are, or may be, infected with HIV. The legislation authorizing the BDLS does not extend to transfusion recipients or to any other individual. Participation in the BDLS by State agencies and blood donation facilities is voluntary, but participants must agree to comply with the provisions of the statute and the regulations as defined in the BDLS final rule.

3. Organization of Information in the Final Rule

One comment suggested that the organization of information in the regulations was confusing, and asked for clarification of the intent of the regulations.

The rule is divided into subsections that provide specific direction on each aspect of the ''lookback'' process. Each subsection of the rule must be reviewed for a complete understanding of all aspects of this important information. The following description serves as a brief overview of the regulations. Section 606.100 (21 CFR 606.100) states the requirements for SOP's, and § 606.160 (21 CFR 606.160) states the requirements for recordkeeping. Section 610.45(d) identifies the circumstances under which the ''lookback'' process shall be initiated. Section 610.46(a) (21 CFR 610.46(a)) states the requirements for the initial steps of the ''lookback'' process. Section 610.46(a)(1) establishes the circumstances for quarantine and requires notification of consignees to

quarantine such products. Section 610.46(a)(2) discusses quarantine of products held by consignees.

Section 610.46(b) specifies the time limit for completion of the licensed, more specific test and the notification of the consignee of those test results. Section 610.46(c) addresses products that are exempt from quarantine and § 610.46(d) discusses requirements for release from quarantine. Section 610.46(e) makes clear that these actions are not considered to be product recalls. Section 610.47(a) (21 CFR 610.47(a)) covers those transfusion services not subject to HCFA's regulations. Section 610.47(b) contains requirements for notification of recipients and § 610.47(c) addresses the notification of a legal representative or relative acting on behalf of the recipient.

B. Comments on § 606.100

Four comments requested more specific direction regarding the content of SOP's.

It is intention of FDA to allow appropriate flexibility to blood establishments in the development of their procedures. For example, as mentioned in one comment, a blood establishment could identify by title or name the individuals authorized to provide and receive consignee notification in the ''lookback'' process. FDA further discusses the content of SOP's in the responses to comments on specific subsections of the rule.

C. Comments on § 610.45(d)

1. Use of Information from Other Sources to Initiate ''Lookback'' Process

One comment stated that there will be additional circumstances when a blood establishment can reliably and consistently receive information that should result in the initiation of a ''lookback'' process. The sources of this information may include the U.S. military, health departments or physicians of former donors now found to be HIV-infected or diagnosed as having AIDS.

FDA agrees that there will be circumstances when the initiation of ''lookback'' may be based on reliable information provided by the U.S. military, health departments, and other sources and recommends appropriate action in those instances. However, a blood establishment generally has no control over whether they will be appropriately contacted by these outside sources. In addition, the laws and procedures governing such notifications will vary from State to State. Therefore, FDA's final rule does not contain specific additional circumstances under which ''lookback'' is required because the ability for each establishment to meet the requirements will vary so widely, based upon varying State laws, local practices, and confidentiality issues.

2. Initiation of ''Lookback'' Process Based on Repeatedly Reactive Screening Results

Three comments objected to the initiation of the ''lookback'' process based on the repeatedly reactive antibody screening test results before the completion of the licensed, more specific test. One comment stated that any ''lookback'' action, beyond the quarantine of product, based on the antibody screening test results would be inappropriate because those tests have a high rate of false positive results and were not intended to be diagnostic without further confirmatory testing.

One comment stated that there is a very high cost associated with preventing the transfusion of very few infectious units based on: (1) The estimate that of all donations made each year, most blood and blood components will be transfused before a donor is permitted to donate again 56 days later; (2) the estimate that only one half of donors will return to donate again; and (3) the very low number of units expected to be infectious despite proper testing.

One comment in support of the rule stated that the rule did not place undue hardship on the blood banking industry. One comment objected to the more stringent requirements for notification due to the current burden of escalating demands and diminishing resources, including increased workload due to more complicated patient illnesses, vacant technical positions that cannot be filled due to the declining numbers of skilled, qualified medical technologists, and hospital costs rising faster than revenues. One comment stated concern that patient needs would not be met because the increased regulation would force hospital based donor centers to close as a result of economic pressures.

One comment cited a threefold increase in the rate of repeatedly reactive screening tests for antibody to HIV with none of those confirmed by Western Blot in the past year, which would result in much higher expected total annualized costs than projected by FDA. Two comments stated that the actual costs would be twice that estimated by FDA. Three comments stated that the goals of the proposed rule are laudable but also estimated that most HIV infections are spread through other modes of transmission and, therefore, our limited health care dollars are better spent in other ways.

FDA is charged with the responsibility of protecting the public from unsafe biological products and has the authority to promulgate regulations to accomplish its public health mission. Comments on the proposed rule indicate that SOP's for the ''lookback'' process are already in place in a large percentage of blood establishments. Based on comments received, FDA believes that the modification of existing SOP's to meet the requirements of this rule would not impose an unreasonable burden or expense to the large number of establishments with an existing system for handling ''lookback'' circumstances.

FDA believes the prevention of a small number of transmissions of HIV per year that will result from the initiation of the ''lookback'' process based on the repeatedly reactive antibody screening test results or other informative test results is a clear benefit. FDA believes that steps must be taken to avoid transfusion of potentially unsuitable Whole Blood and blood components while waiting for the completion of further testing, especially since the time limit for such testing has been extended to 30 days, as described later in this document. FDA recognizes that the requirement for the initiation of this process at the time of the repeatedly reactive HIV antibody test will result in some additional costs to blood establishments that currently do not begin the process at this point. However, FDA believes these steps are warranted to increase the safety of the nation's blood supply.

D. Comments on § 610.46(a)

1. Notification of Consignees

One comment stated concern regarding the notification of consignees of the results of the licensed, more specific test and the potential for confusion if the product in question had already been returned to the blood donor center.

The final rule requires that blood establishments notify consignees to quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes that are at increased risk for transmitting HIV infection. Upon notification by the blood establishment, the consignee is to promptly, within 72 hours, quarantine the affected products until notified of the negative results of a licensed, more specific test. Return of such products to the blood establishment is not a requirement of this rule, and, therefore, should not create confusion. However, if the

consignee does return the blood or blood components to the blood establishment, no further consignee notification would be required. FDA has amended the final rule to clarify the requirement to promptly notify consignees, within 72 hours, for the purpose of identifying those products that remain in inventory and require quarantine.

2. Products for Further Manufacture

One comment concerned § 610.46(a)(2), which requires that unpooled products held by the consignee shall be quarantined. The comment stated that while it appears that the proposed rule is structured to exclude large pools of plasma from some requirements, the rule might be interpreted to have a different result when the collecting facility and the manufacturing facility hold the same license. The comment stated further that in this situation, both large and small pools would be quarantined since the products were not shipped to a consignee to be pooled.

The comment also asked that small pools of plasma intended for further manufacture into noninjectable products also be exempt from quarantine because they are sometimes pooled at the collection facility and may include plasma considered to be in short supply. The comment stated that small pools of plasma intended for the manufacture of noninjectable products should be exempt from quarantine because they are sufficiently safe as noninjectable products.

A collection facility would be required to quarantine all in-house or ''on-site'' Whole Blood, blood components, Source Plasma and Source Leukocytes. A manufacturing facility that shares an establishment license with the collecting facility is not required to quarantine pooled products. To avoid a shortage of injectable and noninjectable products the final rule exempts from quarantine pooled Source Plasma and Source Leukocytes intended for further manufacture into injectable and noninjectable products, as described in § 610.46(c). FDA believes this requirement will better identify those affected products to be quarantine while ensuring the availability of blood products for further manufacture.

Additionally, FDA agrees that pools intended for further manufacture into noninjectable products are sufficiently safe due to their intended use as noninjectable products and are, therefore, exempt from quarantine. The rule has been amended to clarify that Pooled Source Plasma and Pooled Source Leukocytes are exempt from quarantine. Appropriate safeguards must be used to prevent such products intended for further manufacture into non-injectable products from being used for further manufacture into injectable products.

E. Comments on § 610.46(b)

1. Two Week Limit for Completion of Licensed, More Specific Test

One comment supported proposed § 610.46(b) which requires the 2-week time limit for completion of the licensed, more specific test and consignee notification, while twenty-three comments expressed disagreement with the time limit. The 2-week time limit was cited as too short due to shipping of samples, batching of laboratory work, the additional number of tests run when the sample is not negative, dependence upon reference laboratories for this work, and unforeseen circumstances that are beyond the control of the blood establishment. The suggestions for a more appropriate timeframe ranged from 3 weeks to 8 weeks to ''as soon as possible''.

After consideration of the additional information provided in the comment letters, FDA believes that it is appropriate and reasonable to change the time limit for completion of the licensed, more specific test and consignee notification of the test results. FDA is amending § 610.46(b) by allowing a maximum of 30 calendar days for completion of the licensed, more specific test for antibody to HIV and consignee notification of the test results.

FDA's concern for the prompt notification of the transfusion recipient, without undue burden to industry, dictates that the time limit for completion of testing not exceed 30 days. FDA's extension of the time limit for the completion of these steps is intended to give blood establishments a reasonable time period to comply with the regulation. FDA expects that blood establishments will initiate and complete such testing expeditiously, but take no longer than 30 calendar days.

The written SOP's of the establishment required under § 606.100(b)(19) should be adequate to ensure that the required testing and consignee notification is routinely completed within 30 days. In rare circumstances, such as when there are testing problems, testing and notification may take longer than 30 days. In such cases the establishment should document in its records the reason for the failure to meet the requirement. If the establishment frequently fails to meet the required time limits, the establishment should review its procedures to determine how testing and consignee notification can be expedited.

2. Positive Test for Antibody to HIV-2

Two comments on § 610.46(b) requested clarification on further testing and notification of consignee and recipients when donors subsequently test positive for antibody to HIV-2.

In the Memorandum to All Registered Blood Establishments, Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products, dated April 23, 1992, FDA provided guidance recommending that all blood establishments collecting Whole Blood, blood components, Source Plasma, or Source Leukocytes implement a licensed test for detection of antibody to HIV-2 by June 1, 1992. FDA modified existing recommendations for prevention of HIV transmission by blood and blood products to include HIV-2 testing at that time. The revised recommendations for donor testing, deferral, and reentry are found in section II. and the recommendations on ''lookback'' are found in section IV. of the April 23, 1992, memorandum.

This final rule is similar to the FDA guidance on supplemental tests recommended in the April 23, 1992, Memorandum. FDA has amended § 610.46(b) of the final rule to clarify requirements for HIV-2 testing. Currently, there is no ''licensed, more specific'' test for antibody to HIV-2. Thus, the final rule requires the following:

(1) When a donor's screening test for antibody to HIV is repeatedly reactive, a licensed, more specific test for antibody to HIV shall be performed.

(2) When the repeatedly reactive screening test is performed using a single virus test for antibody to HIV–2 or combination test for antibody to HIV–1/HIV–2, a second screening test for HIV–2, which is different from the original HIV–2 test, must also be performed. This second, different enzyme immuno-assay (EIA) test must be a licensed test and can be either a single virus test or a combination test.

Whole Blood, blood components, Source Plasma and Source Leukocytes from prior collections may be released from quarantine only if the donor is tested for antibody to HIV–1 by a licensed, more specific test and the result is negative; and if the screening test is repeated using a different EIA test for antibody to HIV–2, either single virus or combination test, and the result is negative, absent other informative test

results. Release from quarantine is not permitted under any other test results. Transfusion recipient notification is required when the licensed, more specific test for HIV–1 is positive or when the second, different EIA test for antibody to HIV–2 is repeatedly reactive.

Whole Blood, blood components, Source Plasma and Source Leukocytes are exempt from quarantine if the collection occurred more than 12 months prior to the donor's most recent negative screening test(s). If the most recent negative screening test for antibody to HIV was performed prior to the implementation of HIV–2 testing in June of 1992, then the negative screening test for HIV–1 is sufficient to establish the 12-month time period.

This final rule supersedes the existing recommendations for ''lookback'' procedures in section IV. of the April 23, 1992, Memorandum, Exclusion/Retrieval of Potentially Contaminated Units From Prior Collections and Notification of Consignees.

F. Comments on § 610.46 (c) and (d)

1. Release From Quarantine and Western Blot Indeterminate Results

Two comments indicated confusion regarding the disposition of components collected both greater than and less than the 12-month period prior to the most recent nonreactive test result. Additionally, two comments on the subject of Western blot indeterminate results asked for clarification and for exemption from the ''lookback'' process due to what the commentor believes is the unlikely occurrence that a unit with an indeterminate Western blot test result would be infectious.

FDA is requiring prompt quarantine for Whole blood, blood components, Source Plasma and Source Leukocytes collected from a donor at increased risk for transmitting HIV infection. Quarantine is required for units from such a donor collected within the 5years prior to the repeatedly reactive test for antibody to HIV, if intended for transfusion, or collected within 6 months prior to the repeatedly reactive test result, if intended for further manufacture. Section 610.46(c) describes the situation in which Whole Blood, blood components, Source Plasma and Source Leukocytes are exempt from quarantine because there is serological evidence that the donation(s) was not made during the ''window'' period.

In the preamble to the proposed rule, FDA stated that, based on experience, current estimates predict with approximately 95 percent confidence that in all cases of HIV infection, the person will test positive for antibody to HIV by a licensed test within 6 months from the date of infection. As stated in the preamble to the proposed rule, to provide an additional margin of safety, FDA has extended the period for quarantine to 12 months, to more closely approximate a 99 percent confidence interval. Accordingly, FDA's requirement to quarantine all Whole Blood, blood components, Source Plasma and Source Leukocytes collected within 12 months prior to the most recent negative screening test provides an added margin of safety during the months when an infected donor may not yet test positive for antibody to HIV. All donations made before this 12-month period would be outside the ''window'' period and would be exempt from quarantine.

The final rule is amended to clarify the requirements when other informative test results are available. Section 610.46(d) of the final rule states that a product may be released from quarantine if the donor's blood is tested for antibody to HIV by a licensed, more specific test and the test result is negative, absent other informative test results. FDA believes that release from quarantine is possible only if the more specific test is negative and there are no other informative test results that show evidence of HIV infection. This regulation does not allow the release from quarantine following and indeterminate Western blot test result.

Blood establishments may voluntarily perform other FDA approved informative tests for HIV and must consider those test results when determining the status of the donor and the suitability of prior collections. For example, FDA has recently recommended donor screening for HIV–1 antigen(s) using approved tests. Testing for HIV–1 antigen(s) using seroconversion samples has shown that donors with recent HIV infection test repeatedly reactive for antibody to HIV, yet test as negative or indeterminate by a more specific antibody test but positive for HIV–1 antigen(s). Prior collections from such a donor would not be exempt from quarantine unless collected more than 12 months prior to the donor's most recent negative screening test for HIV antibody.

Disposition of prior collections at increased risk for transmitting HIV infection should follow the establishment's SOP for appropriate disposal of blood products that are unsuitable for transfusion, in accordance with § 606.40. The Memorandum to All Registered Blood Establishments from the Director, Center for Biologics Evaluation and Research, Control of Unsuitable Blood and Blood Components, dated April 6, 1988, provides additional guidance for quarantine and disposition of products unsuitable for transfusion.

In situations where an establishment fails to comply within the 30-day limit for completion of further testing, and subsequently the test result is negative, the Whole Blood, blood components, Source Plasma and Source Leukocytes may be released from quarantine and consignees must be notified promptly upon availability of the test results. Destruction of quarantined units is not required merely because further testing was completed after the 30-day deadline. No release of quarantined Whole Blood, blood components, Source Plasma and Source Leukocytes is permitted before the results of the further testing are available.

2. Use of Test Results From Other Laboratories

Two comments asked that blood establishments be allowed to use the laboratory test results from other laboratories as evidence of the most recent negative screening test for antibody to HIV, thus allowing the quarantine and notification to be limited to units collected within 12 months prior to that negative result. One comment stated that evidence of such negative screening results could be provided by independent clinical laboratories, State health departments, military laboratories, other blood banks, etc.

FDA agrees that test results from the Clinical Laboratories Improvement Amendments of 1988 (42 U.S.C. 263a) certified laboratories or licensed blood establishments may be accepted as evidence of the most recent negative screening test for antibody to HIV, provided that the blood establishment has assurance that the laboratory is certified and is using a licensed test kit. The blood establishment should receive and retain testing records documenting the test results.

G. Comments on § 610.47(a)

1. Notification of Transfusion Recipient Prior to Completion of Licensed, More Specific Test

Two comments disagreed with the proposed requirement to notify recipients of potentially infectious units based upon screening results if the licensed, more specific test results are not available within 2 weeks. One comment stated that upon notification, the transfusion recipient would experience unnecessary worry since

more than 90 percent of repeatedly reactive screening results are not confirmed by Western Blot testing.

As previously discussed in this final rule, the time limit for the completion of the licensed, more specific test for HIV and the consignee notification of those test results has been extended from 2 weeks to a maximum of 30-calendar days. This change makes it highly unlikely that complete results will not be available prior to the deadline for notification. If a situation of noncompliance occurs, however, FDA has amended § 610.47(a) so that recipient notification prior to completion of the licensed, more specific test for HIV is not required. This change is consistent with FDA's proposal to notify recipients only if there are positive test results but not when the test results are indeterminate.

FDA agrees that notification of transfusion recipients that the transfused blood or blood component was at increased risk for transmitting HIV is very likely to cause the recipient, and possibly others, extreme anxiety and concern. Based on the rate of repeatedly reactive screening tests that are not confirmed by further testing, a significant percentage of recipients would be subjected to a tentative notification which would prove to be alarming, confusing, and unnecessary. Such recipients would be notified when the increased risk for transmitting HIV has been confirmed by further testing.

2. Establishments Subject to ''Lookback'' Regulations

One comment asked for clarification on § 610.47(a) which addresses those establishments subject to FDA's rule and those hospitals subject to HCFA's rule. Two comments asked if these regulations apply to all regulated blood establishments, including small, hospital-based transfusion services that also draw blood donors. Section 610.47(a) specifically states that transfusion services that are not subject to HCFA's regulations on the conditions of Medicare participation for hospitals (42 CFR part 482) are subject to this rule. FDA inspects establishments where activities include more than the performance of compatibility testing, e.g., blood collection, washing or freezing of red blood cells, and irradiating of blood components. Therefore, small, hospital-based transfusion services that also draw blood donors would be subject to this rule and inspection by FDA. Certain establishments that do not participate in Medicare, such as Indian Health Services and Veteran's Administration hospitals, are also subject to FDA regulations.

HCFA's regulations apply to hospital transfusion services where activities do not include more than the performance of compatibility testing and that participate in Medicare. Section III. of this document describes the division of responsibilities between FDA and HCFA for inspections of blood establishments. HCFA's final rule is published elsewhere in this issue of the Federal Register. This division of responsibilities between FDA and HCFA, consistent with the MOU, eliminates duplication of effort and reduces the burden on blood establishments and hospitals.

H. Comments on § 610.47(b)

1. Clarification of Responsibility for Transfusion Recipient Notification

Two comments asked for clarification as to which entity is responsible for notification of the transfusion recipient or his or her physician in situations where the transfusion services are provided to hospitals by community blood centers. One comment suggested more consistent requirements between FDA and HCFA because it appeared that the HCFA proposal makes the hospital responsible for the notification of the recipient's physician rather than the transfusion service, as is the case in the FDA proposed rule.

It is not the intention of FDA to designate the individual or the department that will contact the recipient but rather to designate that the transfusion service that issues the Whole blood or blood component for transfusion will be ultimately responsible for ensuring that the notification takes place. In a similar manner, HCFA holds the hospital responsible for ensuring the notification is completed.

2. Process and Documentation for Transfusion Recipient Notification

Twenty-five comments expressed concern over the process and timeframe for notification of the transfusion recipient. There were some questions as to where the ultimate responsibility falls for transfusion recipient notification and as to the documentation that is required. Three comments asked that attending physicians be required to comply with these regulations and asked for guidance in situations where the recipient's physician declines to notify the recipient due to conditions such as terminal illness, celibacy, or when the harmful effects may exceed the benefits of notification. Additionally, two comments expressed concern over respect for the doctor-patient relationship and the authority to interfere with that relationship.

As stated previously, FDA intends that each establishment have the flexibility to develop SOP's that describe the steps in this process and all appropriate documentation. The SOP should address documentation of person(s) contacted, by whom, when and whether the physician agreed to notify the recipient, and any additional, pertinent information. Some institutions may choose to designate a specific department or person within the hospital to conduct the notification and counseling for the recipient.

The SOP should be consistent with applicable local and State laws and shall specify both a well designed system for accomplishing notification and the required documentation of the outcome of these efforts.

FDA believes that because the attending physician has developed as relationship with the patient and is most familiar with that patient's history, the patient's interests are best served when the attending physician takes the responsibility for contact and counseling. In those instances when this does not prove to be appropriate or possible, the transfusion service is ultimately responsible for ensuring that the notification takes place. If the patient is competent, but the physician believes the information should not be given to the patient and State law permits a legal representative or relative to receive information on the patient's behalf, then the transfusion service or physician should notify the patient's legal representative or relative. Further, FDA believes that transfusion services should, upon learning of the death of the transfusion recipient, continue the notification process to inform the patient's family. Public health concerns would warrant the notification process continue and include the deceased patient's legal representative or relative. It would not be appropriate for a physician or transfusion service to determine that the patient or someone acting on his or her behalf need not be informed. The final rule has been amended to clarify the notification requirements in §§ 610.46(c) and 610.47(b).

FDA has no regulatory authority over physicians in their role as attending physicians, and for that reason, the agency is not able to require their participation. Upon accepting responsibility for recipient notification and counseling, it is reasonable to expect that the physician would, in good faith, determine the appropriate

content and completeness of information provided to the recipient.

FDA is relying on HCFA's expertise in the area of hospital practice in setting time limits for transfusion recipient notification. Consistent with HCFA's final rule, published elsewhere in this issue of the Federal Register, FDA believes that the hospital's notification effort should consist of, at the minimum, three attempts by telephone or in writing to reach the recipient, the recipient's legal representative or relative. The final rule has been amended to clarify that the transfusion service's notification effort should begin immediately after receiving results of further testing for HIV and should be completed 8 weeks later. The rule has also been amended to clarify that the transfusion service should notify the patient, the patient's legal representative or relative, as appropriate.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation in necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order, and has determined that this is not a significant regulatory action.

The purpose of the ''lockback'' requirement is to reduce the risk of transfusion transmitted HIV infection through the quarantine of blood and blood components that might have been collected during the ''window'' period, when the antibody to HIV is not yet detectable by a screening test. Notification of consignees to quarantine the affected products, until a more specific test for antibody to HIV is completed, will prevent any further transmission of the virus. Upon completion of more specific testing, all recipients of prior collections from a donor that subsequently tests positive for antibody to HIV will be notified by their attending physician, when possible, or by the transfusion service. Such transfusion recipients shall receive notification for the purpose of testing for evidence of HIV infection, early treatment, if indicated, and counseling to take appropriate precautions to prevent the further spread of the virus such as to sexual partners.

Most blood establishments already participate in a ''lookback'' program. Ninety-five percent of blood establishments, collecting 98 percent of the nation's blood supply, already participate in a ''lookback'' notification of their customers to quarantine previously shipped blood later determined to be at increased risk for transmitting HIV. Thus, requirements for written procedures, records of consignee notification, and records that relate the prior collections to the donor, later found to be repeatedly reactive for antibody to HIV, would affect at most about 5 percent of blood establishments; the remaining establishments may need to make minor changes to their existing procedures. Therefore, FDA believes this final rule should have a minimal impact. FDA expects the total annualized cost of the final rule to blood establishments to be $3,248,354. FDA anticipates only a small number of cases per year that will involve transfusion recipient notification. In conclusion, FDA has determined that the final rule is not a significant regulatory action as defined in Executive Order 12866.

At the time of the proposed rule, the agency certified that the proposed requirements would not have a significant impact on a substantial number of small entities. However, in response to industry comments and in light of amended requirements for analyzing impact on small entities (as enacted by Pub. L. 104–121), it was determined that a final regulatory flexibility analysis would be useful. Accordingly, the agency has assessed this final rule in accordance with the Regulatory Flexibility Act, with the following results:

Need for, and objective of, the rule. As described elsewhere in this preamble, FDA is taking this action to help ensure the continued safety of the blood supply, and to help ensure that information is provided to consignees of Whole Blood, blood components, Source Plasma and Source Leukocytes and to recipients of Whole Blood and blood components from a donor whose subsequent donation test positive for antibody to HIV.

Types and number of small entities affected. This rule will affect all of the 3,015 registered U.S. blood establishments. Of these registered establishments, approximately 400 are part of the American Red Cross, which supplies approximately 45 percent of blood products nationally. An additional 286 are Federal or State facilities. Many, or most, of the remaining 2,204 establishments may be small entities as defined by the Regulatory Flexibility Act.

The affect of this rule is greatest for those blood establishments that have not already voluntarily implemented ''lookback'' procedures similar to those required here. As stated in the proposed rule (58 FR 34962), FDA estimated that at least 95 percent of establishments, supplying 98 percent of the nation's blood, have such voluntary procedures and would need to make only minor changes to ensure that they are in compliance with this rule. The remaining up to 150 establishments would require more substantial changes in their procedures. FDA considers 150 to be an upper bound, since it is likely that liability concerns and advances in automated data technology have prompted most establishments that did not previously have ''lookback'' procedures to have them in place by now.

Projected reporting, recordkeeping, and other compliance requirements. To comply with this rule, all blood establishments subject to this rule, including small entities, must: (1) Review and, if necessary, modify their SOP's; (2) maintain the necessary records to carry out these procedures; and (3) notify consignees within 72 hours of repeatedly reactive test results. Blood establishments that provide transfusion services and that are not subject to HCFA regulations must also notify physicians of prior donation recipients, or the recipients themselves, of the need for HIV testing and counseling. The estimated time needed for establishments to comply with the reporting, disclosure, and recordkeeping requirements of this rule are described in detail in the reporting and recordkeeping tables in section VII. of this document.

FDA estimates that two types of skills will be necessary to meet these reporting and recordkeeping requirements. The skills of a medical technologist, or a person with equivalent training and experience, will be necessary to record donor, quarantine, testing, and disposition information, and to notify consignees of test results. Updating SOP's and notifying physicians and recipients of test results will require a person knowledgeable and experienced in medical laboratory practice.

Based on the reporting, disclosure, and recordkeeping burden described in section VII. of this document, FDA estimates that establishments that currently have ''lookback'' procedures will require approximately 27 hours per year to bring their procedures into compliance with this rule, while establishments without such procedures will require approximately 40 hours

annually to complete the required tasks. Establishments whose transfusion services are also covered by this rule will require an additional 8 hours per year to comply. Based on an estimated average hourly cost of $37.98 to perform the required tasks, FDA predicts that the average annual cost of these requirements for establishments that currently lack ''lookback'' procedures is $1,520 per facility for most establishments and $1,820 for facilities that transfuse as well as collect blood. Average annual costs for the great majority of establishments that already have ''lookback'' procedures are expected to be approximately $1,030 for most establishments and $1,340 for covered establishments that also provide transfusions.

In addition to these reporting and recordkeeping costs, all facilities will bear the additional cost of disposing of any affected units; conducting licensed, more specific tests for HIV; and replacing discarded units.

With the exception of the initial development of SOP's, all costs related to implementing the requirements of this rule are related to the number of units of blood collected from repeat donors who test positive for HIV, which in turn is related to total blood collections. The average number of units of blood drawn per establishment covered by this rule is approximately 8,000 units per year. Smaller establishments will have lower costs of compliance than the averages described above, while larger blood facilities will have higher costs, in proportion to the number of units of blood drawn per year.

Steps to minimize the economic impact on small entities. The significant issues raised by public comments on the costs of putting in place the required procedures, and the burdens imposed by the timeframes in the proposed rule, are described elsewhere in this preamble, FDA agrees with the numerous comments suggesting that 2 weeks is too short a time period to allow for completion of the licensed, more specific test and subsequent notification of consignees, and that 4 weeks is a more reasonable period. Accordingly, FDA has amended the rule to allow 30 calendar days for the completion of these tasks. This change should reduce the impact of the rule on small entities and reduce the chance that blood transfusion recipients will fail to receive notification that they had received blood or blood components that are at increased risk of transmitting HIV infection and or fail to receive appropriate counseling. In response to another comment, FDA amended the proposed rule to specify that certain pooled blood products intended for further manufacture into noninjectable products are exempt from quarantine. This change should also reduce the burden of the rule on some small entities. FDA rejected the option of excluding all small entities from the rule, because to do so would exempt a substantial proportion of establishments and defeat the objective of ensuring that all establishments have appropriate procedures in place to ensure the continued safety of the blood supply.

FDA's selection of the regulatory option described in this rule is based on its legal authority under sections 351 and 361 of the Public Health Service Act and section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351). The need for regulatory action results from the fact that a small but significant number of new HIV infections each year continue to be transmitted through blood transfusions; the fact that a small minority of blood establishments still lack appropriate procedures for identification of blood products at increased risk for transmitting HIV infection and notification of recipients of such products; and the need to ensure that those establishments with voluntary ''lookback'' procedures in place have procedures that are adequate and vigorously followed. The primary policy consideration in the formulation of this rule is to protect the public health.

VII. Paperwork Reduction Act of 1995

This final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing procedures, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection.

Description: The final rule requires that blood establishments prepare and follow written procedures when the blood establishments have collected Whole Blood, blood components, Source Plasma and Source Leukocytes later determined to be at risk for transmitting HIV infections. This final rule requires that when a donor who previously donated blood is tested in accordance with § 610.45 on a later donation, and tests repeatedly reactive for antibody to HIV, the blood establishment shall perform more specific testing using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma or Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients. The agency is issuing this final rule to help ensure the continued safety of the blood supply, to help ensure that information is provided to users of blood and blood components, and to help ensure that transfusion recipients of blood and blood components at risk for transmitting HIV will be notified as appropriate.

Description of Respondents: Blood establishments (Business and Not-for-Profit).

Individuals and organizations had an opportunity to comment on the information collection requirements in the proposed rule. FDA has revised these estimates based on current data. These estimates are an approximation of the average time expected to be necessary for the collection of information. They are based on such information as is available to FDA. There are no capital costs, or operating and maintenance costs associated with this information collection.

As required by the Paperwork Reduction Act of 1995, FDA will submit a copy of this rule to OMB for review and approval of these information requirements. Individuals and organizations may submit comments on the information collection requirements by November 8, 1996. FDA particularly invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the collection of information, including the validity of the methodology and assumption 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. Comments

should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, make revisions as necessary to the information collection requirements, and submit the requirements to OMB for review and approval. Additional time will be allotted for public comment to OMB on the requirements and OMB review. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection requirements. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

ESTIMATED ANNUAL REPORTING/DISCLOSURE BURDEN

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
610.46(a)	3,015	60	180,900	.17	30,753
610.46(b)	3,015	60	180,900	.17	30,753
610.47(b)	200	16	3,200	.5	1,600
Total					63,106

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
606.100(b)(19)	3,015	1	3,015	2	6,300
606.160(b)(1)(vii)	150	160	24,000	12.8	1,920
606.160(b)(1)(viii)	3,015	60	180,900	4.8	14,472
Total					22,422

VIII. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 606 and 610 are amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 505, 510, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 360 360j, 371, 374); secs. 215, 351, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263a, 264).

2. Section 606.100 is amended by adding new paragraph (b)(19) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) * * *

(19) Procedures in accordance with § 610.46 of this chapter to look at prior donations of Whole Blood, blood components, Source Plasma and Source Leukocytes from a donor who has donated blood and subsequently tests repeatedly reactive for antibody to human immunodeficiency virus (HIV) or otherwise is determined to be unsuitable when tested in accordance with § 610.45 of this chapter. Procedures to quarantine in-house Whole Blood, blood components, Source Plasma and Source Leukocytes intended for further manufacture into injectable products that were obtained from such donors; procedures to notify consignees regarding the need to quarantine such products; procedures to determine the suitability for release of such products from quarantine; procedures to notify consignees of Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors of the results of the antibody testing of such donors; and procedures in accordance with § 610.47 of this chapter to notify attending physicians so that transfusion recipients are informed that they may have received Whole Blood and, blood components at increased risk for transmitting human immunodeficiency virus.

* * * * *

3. Section 606.160 is amended by adding paragraphs (b)(1)(vii) and (b)(1)(viii) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(vii) Records to relate the donor with the unit number of each previous donation from that donor.

(viii) Records of quarantine, notification, testing, and disposition performed pursuant to §§ 610.46 and 610.47 of this chapter.

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

4. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

5. Section 610.45 is amended by adding a new paragraph (d) to read as follows:

§ 610.45 Human immunodeficiency virus (HIV) requirements.

* * * * *

(d) For a donor whose test results for antibody to HIV are repeatedly reactive or otherwise determined to be unsuitable when tested in accordance with paragraph (a) of this section, the blood establishment shall comply, as applicable, with §§ 610.46 and 610.47.

6. New §§ 610.46 and 610.47 are added to subpart E to read as follows:

§ 610.46 ''Lookback'' requirements.

(a) *Quarantine and notification.* (1) All blood and plasma establishments are required to take appropriate action when a donor of Whole Blood, blood components, Source Plasma and Source Leukocytes tests repeatedly reactive for antibody to human immunodeficiency virus (HIV), or otherwise is determined to be unsuitable when tested in accordance with § 610.45. For Whole Blood, blood components, Source Plasma and Source Leukocytes collected from that donor within the 5 years prior to the repeatedly reactive test, if intended for transfusion, or collected within the 6 months prior to the repeatedly reactive test, if intended for further manufacture into injectable products, except those products exempt from quarantine in accordance with § 610.46(c), the blood establishment shall promptly, within 72 hours:

(i) Quarantine all such Whole Blood, blood components, Source Plasma and Source Leukocytes from previous collections held at that establishment; and

(ii) Notify consignees of the repeatedly reactive HIV screening test results so that all Whole Blood, blood components, Source Plasma and Source Leukocytes from previous collections they hold are quarantined.

(2) Consignees notified in accordance with paragraph (a)(1)(ii) of this section shall quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes held at that establishment except as provided in paragraph (c) of this section.

(b) *Further testing and notification of consignees of results.* Blood establishments that have collected Whole Blood, blood components, Source Plasma or Source Leukocytes from a donor as described in paragraph (a) of this section shall perform a licensed, more specific test for HIV on the donor's blood, and in the case of distributed products, further shall notify the consignee(s) of the results of this test, within 30 calendar days after the donor's repeatedly reactive test. Pending the availability of a licensed, more specific test for HIV–2, a second, different screening test for antibody to HIV–2 shall be used along with a licensed, more specific test for HIV–1.

(c) *Exemption from quarantine.* Products intended for transfusion need not be held in quarantine if a determination has been made that the Whole Blood, blood components, Source Plasma or Source Leukocytes was collected more than 12 months prior to the donor's most recent negative antibody screening test when tested in accordance with § 610.45. Pooled Source Plasma and Source Leukocytes are exempt from quarantine.

(d) *Release from quarantine.* Whole Blood, blood components, Source Plasma and Source Leukocytes intended for transfusion or further manufacture which have been quarantined under paragraph (a) of this section may be released if the donor is subsequently tested for antibody to HIV as provided in paragraph (b) of this section and the test result is negative, absent other informative test results.

(e) Actions under this section do not constitute a product recall as defined in § 7.3(g) of this chapter.

§ 610.47 ''Lookback'' notification requirements for transfusion services.

(a) Transfusion services that are not subject to the Health Care Financing Administration's regulations on conditions of Medicare participation for hospitals (42 CFR part 482) are required to take appropriate action in accordance with paragraphs (b) and (c) of this section when a recipient has received Whole Blood or blood components from a donor determined to be unsuitable when tested for human immunodeficiency virus (HIV) infection in accordance with § 610.45 and the results of the additional tests as provided for in § 610.46(b) are positive.

(b) *Notification of recipients of prior transfusion.* If the transfusion service has administered Whole Blood or blood components as described in paragraph (a) of this section, the transfusion service shall notify the recipient's attending physician (physician of record) and ask him or her to inform the recipient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the recipient, the transfusion service shall notify the recipient and inform the recipient of the need for HIV testing and counseling. The notification process shall include a minimum of three attempts to notify the recipient and be completed within a maximum 8 weeks of receipt of the result of the licensed, more specific test for HIV. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling, and shall document the notification or attempts to notify the attending physician or the recipient, pursuant to § 606.160 of this chapter.

(c) *Notification to legal representative or relative.* If the transfusion recipient has been adjudged incompetent by a State court, the transfusion service or physician must notify a legal representative designated in accordance with State law. If the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, the transfusion service or physician must notify the recipient or his or her legal representative or relative. If the transfusion recipient is deceased, the transfusion service or physician must continue the notification process and inform the deceased recipient's legal representative or relative. Reasons for notifying the recipient's relative or legal representative on his or her behalf shall be documented pursuant to § 606.160 of this chapter.

Dated: July 11, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–22709 Filed 9–6–96; 8:45 am]

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Health Care Financing Administration

42 CFR Part 482

[BPD–633–F]

RIN 0938–AE40

Medicare and Medicaid Programs; Hospital Standard for Potentially HIV Infectious Blood and Blood Products

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule requires hospitals participating in the Medicare and Medicaid programs to take appropriate action when the hospitals learn that they have received whole blood, blood components (including recovered plasma), source plasma, and source leukocytes (hereafter referred to as blood or blood products) that are at increased risk of transmitting Human Immunodeficiency Virus (HIV)