DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 45 and 52

Federal Acquisition Regulations (FAR); Use of Property Clauses in Service Contracts

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council are considering changes to Federal Acquisition Regulations (FAR) 45.103, 45.106 and 52.245–4 to clarify the contractor's responsibility for Government-furnished property under service contracts performed at Government installations.

Comments: Comments should be submitted to the FAR Secretariat at the address shown below on or before April 22, 1986, to be considered in the formulation of a final rule.

ADDRESS: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets NW., Room 4041, Washington, DC 20405.

Please cite FAR Case 85–75 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret A. Willis, FAR Secretariat, Telephone (202) 523–4755.

SUPPLEMENTARY INFORMATION:

A. Background

Questions have arisen concerning contractor responsibility for Government-furnished property during the performance of service contracts when the property is located at Government installations where the contractor has less than full control over the property. The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council have determined that under this circumstance the Government should be responsible for the property and propose to revise FAR 45.103, 45.106 and 52.245–4 to reflect this policy.

B. Regulatory Flexibility Act Analysis Summary

Economic Impact of Proposed Rule

Incorporation of the proposed rule in the Federal Acquisition Regulation may result in a significant economic impact on a substantial number of small entities. However, information currently available is insufficient to permit a determination as to the extent of such economic impact, and comments that will permit a determination are hereby solicited.

Alternatives to the Proposed Rule

The proposed rule is expected to have a favorable economic impact on small entities. The proposed language should lower contract costs and encourage small and disadvantaged businesses to compete.

C. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 96–511) does not apply because the proposed changes to FAR 45.103, 45.106, and 52.245–4 clarify the contractor's responsibility for Government-furnished property and do not impose any additional reporting or recordkeeping requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501 et seq.

List of Subjects in 48 CFR Parts 45 and 52

Government procurement.

Dated: February 14, 1986.

Lawrence J. Rizzi,

Director, Office of Federal Acquisition and Regulatory Policy.

Therefore, it is proposed that 48 CFR Parts 45 and 52 be amended as set forth below:

1. The authority citation for Parts 45 and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c).

PART 45—GOVERNMENT PROPERTY

2. Section 45.103 is amended by removing in paragraph (b)(2) the word "or"; by removing in paragraph (b)(3) the period at the end of the sentence and inserting in its place the words "; or" and by adding paragraph (b)(4) to read as follows:

§ 45.103 Responsibility and liability for Government property.

* * * * *

(b) * * *

(4) Negotiated or sealed bid service contracts performed on a Government installation where the contracting officer determines that the contractor has little direct control over the Government property because it is located on a Government installation and is subject to accessibility by personnel other than the contractor's employees and that by placing the risk on the contractor, the cost of the contract would be substantially increased.

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3. Section 45.106 is amended by revising paragraph (b)(2) and paragraph (d) to read as follows:

§ 45.106 Government property clauses.

* * * * *

(b) * * *

(2) If the contract is (i) a negotiated fixed-price contract for which prices are not based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation or (ii) a fixed-price service contract which is performed primarily on a Government installation, provided the contracting officer determines it to be in the best interest of the Government (see § 45.103(b)(4)), the contracting officer shall use the clause with its Alternate I.

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(d) The contracting officer may insert the clause at 52.245–4, Government-Furnished Property (Short Form), in solicitations and contracts when a fixed-priced, time-and-material, or labor-hour contract is contemplated and the acquisition cost of all Government-furnished property to be involved in the contract is $50,000 or less unless a contract with an educational or nonprofit organization is contemplated.

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PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. Section 52.245–4 is amended by revising the introductory text to read as follows:

§ 52.245–4 Government-Furnished Property (Short Form).

As prescribed in 45.106(d), insert the following clause:

* * * * *

[FR Doc. 86–3710 Filed 2–20–86; 8:45 am]

BILLING CODE 6820–61–M

Federal Register

Friday
February 21, 1986

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 606, 610 and 640

General Biological Products Standards, Additional Standards for Human Blood and Blood Products; Serologic Test for Antibody to Human T-Lymphotropic Virus Type III (HTLV-III); Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 610, and 640

[Docket No. 85N-0032]

General Biological Products Standards, Additional Standards For Human Blood and Blood Products; Serologic Test For Antibody to Human T-Lymphotropic Virus Type III (HTLV-III)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations to require that each unit of human blood and blood components intended for use in preparing a product be tested and found nonreactive by an approved serologic test for antibody to human T-lymphotropic virus type III (HTLV-III), using the licensed reagent "Human T-Lymphotropic Virus Type III." HTLV-III is believed to be the etiologic agent of acquired immunodeficiency syndrome (AIDS). FDA believes that the routine testing of blood by an approved serologic test for antibody to HTLV-III should decrease the risk of transmitting AIDS by the transfusion of blood and blood components and by the parenteral use of certain plasma derivatives.

DATES: Written comments by March 24, 1986. FDA is proposing that any final rule based on this proposal be effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steve F. Falter, Center for Drugs and Biologics (HFN-364), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: Under the Public Health Service Act (42 U.S.C. 262), FDA is proposing to amend the biologics regulations (21 CFR Parts 606, 610, and 640) to require that each donation of blood or blood components intended for use in a biological product be tested by a serologic test for antibody to HTLV-III approved for such use by the Director, Office of Biologics Research and Review (OBRR). The proposed requirements would apply to all blood and blood components intended for use in preparing any product, including products not subject to licensure, such as in vitro diagnostic reagents derived from human blood source material. Accumulated evidence has shown that HTLV-III, also called lymphadenopathy-associated virus (LAV), is the probable etiologic agent of AIDS. Currently, the only approved serologic test for HTLV-III detects antibody to HTLV-III.

The test uses a reagent licensed under the Public Health Service Act with the proper name "Human T-Lymphotropic Virus Type III." FDA is proposing to use the general term "a serologic test for HTLV-III" in the regulations so that any improved test developed in the future may be put into use immediately upon approval by the Director, OBRR, without further amendment of the regulations being required. Routine screening of blood by a serologic test for HTLV-III is expected to decrease the risk of transmitting AIDS by blood transfusion and parenteral use of other products derived from blood.

Throughout this proposed rule, FDA is using the proper names for biological products established in a final rule published in the **Federal Register** of January 29, 1985 (50 FR 4128); effective January 29, 1986.

I. Background

AIDS is a serious, often fatal, disease affecting the immune system. AIDS is known to be transmitted by contact with the blood or semen of a person carrying the virus. Certain population groups are at a higher risk than the general population for contracting AIDS. These high-risk groups include any male who has had sex with a male since 1977, abusers of intravenous drugs, hemophiliacs, and the sexual partners of individuals in a high-risk group. A donor carrying HTLV-III may also transmit the virus to another person by transfusion of blood or a blood component or by the parenteral administration of certain high-risk plasma derivatives made from the donor blood, such as Antihemophilic Factor. Only a small fraction, slightly more than 2 percent, of the persons with AIDS are believed to have contracted the illness from blood and blood products carrying HTLV-III. Nevertheless, the potential for blood, blood components, and blood products to transmit HTLV-III virus has caused great concern within the Department of Health and Human Services, the blood bank community, plasma collection centers, and among the users and recipients of blood and blood products.

In early 1983, FDA issued letters to all establishments that collect blood and blood components or use blood components for further manufacture into blood derivatives. The letters contained recommendations to decrease the potential risk of transmitting HTLV-III virus by transfusion or by the use of certain plasma derivatives. Basically the recommendations were to: (1) Provide educational material relating to AIDS so that donors would know when they were in a high-risk group; (2) screen donors by history and examination for the early signs and symptoms of AIDS and AIDS-related conditions; and (3) advise donors that members of high-risk groups should voluntarily exclude themselves from donating. FDA updated these recommendations in December 1984 (Ref. 1). Blood establishments are continuing to follow these recommendations. However, because apparently healthy individuals unknowingly may be carrying the AIDS virus in their blood, some cases of transfusion-related AIDS and AIDS transmitted by certain plasma derivatives will continue to occur.

In early 1984, scientists at the National Institutes of Health published evidence that HTLV-III was the probable etiologic agent of AIDS (Ref. 2). The scientists also identified a laboratory test for detecting antibody to HTLV-III (Ref. 3). The Department of Health and Human Services, recognizing that the laboratory test could be used for the routine screening of blood by blood banks and plasma centers published a notice in the **Federal Register** of May 3, 1984 (49 FR 18899), soliciting applications to develop and distribute an assay system for the detection of antibody to HTLV-III. Five applicants were selected, and they immediately began to develop and test the assay system. FDA has issued a license to the five manufacturers to manufacture the reagent, Human T-Lymphotropic Virus Type III, to be used in the text system to detect antibody to HTLV-III. In the near future, FDA may license other manufacturers of the reagent. Adequate supplies of the licensed reagent are now available to perform routine testing of blood to detect antibody to HTLV-III by blood banks and plasma centers. Indeed, such establishments already have begun testing donor blood for antibody to HTLV-III.

It is important to note that the available test system detects human antibody to HTLV-III produced in response to exposure to the HTLV-III virus. The test does not detect the presence of the virus itself. In several studies, HTLV-III has been recovered from a high percentage of individuals in high-risk groups who concurrently have detectable antibody to HTLV-III (Refs. 4 and 5). Similarly, from 22 to 87 percent

of asymptomatic persons in various high-risk groups were found to have detectable antibody to HTLV-III (Refs. 6 through 13). In contrast, antibody to HTLV-III has been detected in less than 1 percent of asymptomatic individuals not known to be in a high-risk group (Refs. 3, 6, 7, 8, 14, 15, and 16). Recent limited studies suggest that HTLV-III can be isolated from some asymptomatic individuals who do not have detectable antibody to the virus (Refs. 17 and 18). This would be expected, for example, during the early stage of infection when the body's immunologic defense system has not had time to develop the antibody. Therefore, FDA expects that routine use of this test will reduce greatly the possibility of transmitting the HTLV-III virus by transfusion or parenteral use of certain plasma derivatives, but testing may not eliminate completely the occurrence of such cases.

Results are not yet available from a study designed to provide information concerning the significance of antibody-positive results for asymptomatic individuals, such as blood donors, who are not known to be in a high-risk group. Based on the available information, FDA expects that the routine screening of blood and blood components for antibody to HTLV-III should decrease the risk of transmitting AIDS by transfusion or by parenteral use of blood products.

FDA is proposing in these regulations only the appropriate requirements for the proper testing and labeling of blood necessary to assure the continued safety of blood, blood components, and blood products. In the *Morbidity and Mortality Weekly Report* of January 11, 1985 (Ref. 19), the Public Health Service (PHS) has provided provisional recommendations concerning testing for antibody to HTLV-III and the interpretation and implications of serologic test results. On February 19, 1985, FDA issued a letter to all registered blood establishments providing additional advice for implementing the PHS provisional recommendations (Ref. 20). FDA updated these recommendations by a letter to all blood establishments dated May 7, 1985 (Ref. 21). On May 25, 1985, PHS published recommendations concerning the testing of donors of organs, tissues, and semen for antibody to HTLV-III (Ref. 22).

II. Proposed Amendments to The Regulations

To assure proper understanding of this discussion and the proposed rule, FDA is defining certain terms applicable to the test for antibody to HTLV-III as follows. During routine testing, each blood sample is tested according to the directions supplied by the manufacturer of the test kit and, as described in the directions, each sample is determined to be *reactive* or *nonreactive*. A reactive result indicates the possible presence of HTLV-III antibody in the sample. Reactive samples are tested again and a sample that is found to be reactive on two independent assays is considered to be *repeatedly reactive*. A sample is considered to be *positive* for antibody to HTLV-III when it has tested repeatedly reactive.

In the following paragraphs, FDA is discussing each of the proposed amendments to the regulations:

A. Instruction Circular

In the **Federal Register** of August 30, 1985 (50 FR 35458), FDA published a final rule that revised the labeling requirements for blood and blood components. The final rule becomes effective on September 2, 1986. In that final rule, FDA codified under § 606.122 requirements for the content of an instruction circular that must be made available to users of blood and blood components intended for transfusion. The instruction circular provides the users with the information necessary for the proper use of blood and blood components. FDA believes that the results of the serologic test for HTLV-III are necessary information of which the user should be made aware. Accordingly, FDA is proposing to amend § 606.122(e) to require that blood establishments revise their instruction circulars to include a statement that all blood products are nonreactive by a serologic test for HTLV-III. Although FDA is not proposing to require a specifically worded statement, the agency recommends that all instruction circulars be consistently worded. Accordingly, FDA recommends that either of the following statements be included on the instruction circular: "Nonreactive by serologic test for HTLV-III," or, if combined with the existing statement concerning hepatitis B testing, "Nonreactive when tested for HBsAg and HTLV-III by FDA required tests." FDA also recommends that either of these statements be included on the container label of Source Plasma (see paragraph II. G. of this preamble) or other blood and blood components intended for further manufacture.

FDA proposes to require that the instruction circular be revised to include the proposed statement by 30 days after the date of publication in the **Federal Register** of a final rule resulting from this proposal. In lieu of reprinting the entire circular, blood establishments may stamp or type an appropriate statement on existing instruction circulars in accordance with the proposed requirement. FDA believes that blood establishments will have revised printed labeling including the proposed statement in use within 1 year after the date of publication in the **Federal Register** of a final rule resulting from this proposal.

FDA believes that most blood establishments will begin routine tests of blood and blood components for antibody to HTLV-III before any final rule based on this proposal is published in the **Federal Register**. FDA recommends that each blood establishment notify the users of its products in writing of the date of initiation of the routine testing program and revise their instruction circular to include one of the proposed statements. Licensed blood establishments should submit to the Director, OBRR, a copy of the revised instruction circular at the time of its distribution.

The instruction circular and Source Plasma label statements recommended in the proposed rule are identical with the labeling statements recommended by FDA for use during the voluntary phase of the testing program (Ref. 20). FDA recognizes that the phrase "by FDA required tests" used in one of the recommended labeling statements is inaccurate during the time that use of the serologic test for HTLV–III is voluntary. However, FDA decided to permit this minor inaccuracy so that blood establishments will not be required to relabel their products at the time the test becomes mandatory.

The proposed rule would require that all source blood and blood components used to manufacture blood derivatives be nonreactive to a serologic test for HTLV–III and labeled as nonreactive to the HTLV–III test. However, FDA is not proposing to require that labeling for each of the various blood derivatives manufactored from blood and blood components contain a similar statement that the source materials used to make the products were tested for HTLV–III and found nonreactive. FDA is confident that by the time a final rule based on this proposal is published, manufacturers of derivatives at risk for transmitting HTLV virus will be using voluntarily only source materials found nonreactive to a serologic test for HTLV–III. Therefore, FDA has decided not to require use on labeling for blood derivate products of a standard labeling statement that the derivative product was prepared from source materials found nonreactive to a serologic test for HTLV–III, because such a labeling

requirement would provide no information to users that is essential for the proper use of the products. FDA intends to permit manufacturers to voluntarily amend product labeling for derivatives to include such information.

Manufacturers of licensed in vitro diagnostic products label their products with general cautionary statements such as "Caution: Human Blood Was Used in Manufacturing this Product. Handle as if Capable of Transmitting Infectious Agents." Accordingly, FDA is not proposing labeling changes for in vitro diagnostic products at this time.

B. HTLV–III Testing Requirements

FDA is proposing to add § 610.45 *HTLV–III requirements* that would include: (1) testing requirements; (2) requirements concerning who may perform the test; and (3) restriction on the use of products testing positive by a serologic test for HTLV–III.

In proposed § 610.45(a), FDA is proposing to require that each unit of human blood or blood components intended for use in preparing a biological product to be tested by a serologic test for HTLV–III approved for such use by the Director, OBRR. Currently, FDA has approved only the test for detecting antibody to HTLV–III. FDA would permit testing establishments to put into use the approved test for detecting antibody to HTLV–III without further FDA approval, provided the test method is used as recommended by the manufacturer of the licensed reagent.

Proposed § 610.45(a) would provide that a blood establishment may issue blood and blood components before the serologic test for HTLV–III is completed under circumstances approved in writing by the Director, OBRR, providing the testing is completed as soon as possible thereafter. This provision would allow for the manufacture of certain highly perishable blood products, such as interferon, which are manufactured from source leukocytes (whire blood cells). For optimal production, interferon should be manufactured within 24 hours after the leukocytes are collected. Performance of the complete HTLV–III test before shipping the leukocytes may not provide sufficient time to ship the leukocytes to the manufacturing site. To obtain FDA approval for shipment prior to completion of testing, the agency would require that both the collection and manufacturing facility establish specific procedures for collection, shipment, and quarantine of a blood product before testing is completed. FDA has in § 610.40(b)(4) a similar provision applicable to the testing of blood and blood components for hepatitis B surface antigen (HBsAg). (See the **Federal Register** of June 29, 1984; 49 FR 26717).

In proposed §§ 610.45(a), FDA also is proposing to permit blood establishments to issue blood and blood products in dire emergencies before the results of a serologic test for HTLV–III are available. FDA considers a "dire emergency" to be a life-threatening situation where the patient's need for the blood or blood components is so acute as to preclude the completion of testing before administration of the blood or blood components. The proposed language is consistent with current requirements in 21 CFR 610.40(b)(4) that apply to the testing of blood of hepatitis B surface antigen (HBsAg).

FDA is proposing to amend existing § 640.2(f) to reference the testing requirements of proposed 610.45(a). (FDA revised § 640.2(f) previously in the final rule of August 30, 1985.) Section 640.2(f) prescribes procedural requirements applicable to blood and blood components intended for transfusion that are issued before one or more of the tests required by the regulations are completed. Establishments issuing blood and blood components in a dire emergency in accordance with § 610.45(a) would also be required to meet the requirements of § 640.2(f).

FDA notes that tests systems other than the currently approved test are being developed to detect antibody to HTLV–III. These test systems, such as the Western blot method, are very useful for research purposes but are not suitable at this time for routine use for screening large numbers of samples. At this time, FDA is neither requiring nor specifically recommending that the Western blot method be used for testing donor blood. FDA believes that the test methods and reagents of these systems need further standardization and the available data are incomplete concerning the sensitivity and reliability of these tests.

c. Testing Responsibility

In proposed § 610.45(b), FDA is proposing to permit qualified establishments other than the collecting establishments to perform the serologic test for HTLV–III. This proposed amendment is consistent with current requirements in 21 CFR 610.40(b) that apply to the testing of blood for HBsAg.

D. Restrictions on Use

In proposed § 610.45(c), FDA is proposing to require that blood and blood components that are positive to a serologic test for HTLV–III, or collected from a donor known to be positive to a serologic test for HTLV–III, may not be used for preparing any product, including products not subject to licensure, except as described below. FDA recognizes that valuable diagnostic or therapeutic agents may be developed in the future for which blood or blood components containing antibody to HTLV–III are essential source materials. However, FDA believes that inappropriate handling, labeling, or use of such blood could be hazardous to the public health. Therefore, FDA is proposing to restrict the use of blood and blood components containing antibody to HTLV–III to assure that FDA may adequately monitor the handling, labeling, and use of such blood and blood components.

Under proposed § 610.45(c)(1), blood establishments intending to distribute blood or blood components positive to a serologic test for HTLV–III would apply for approval to the Director, OBRR. The written application would describe the intended use of the positive blood, including identification of all consignees and the procedures for collecting, handling, labeling, and shipping the blood.

Under proposed § 610.45(c)(2), FDA would not apply these restrictions to certain cases when the positive blood or blood components are not intended for commercial distribution or for use in preparing a product. Such cases include: (1) The distribution of small blood, plasma, or serum samples, if not intended for use in manufacturing a product; (2) the in-house use of positive blood and blood components for research purposes; and (3) the noncommercial distribution of blood and blood components for research purposes. FDA believes that the proposed restrictions will assure the continued public health while not impeding continuing research efforts directed toward AIDS.

E. Laboratory Tests and Testing the Blood (§§ 640.5, 640.14, 640.23, 640.33, 640.53)

FDA is proposing to amend the sections listed above to reference the testing requirements in § 610.45(a). In § 640.5, FDA proposes to add paragraph (f) to reference the testing requirements in § 610.45. In effect, FDA is proposing to require that the source blood of all blood and blood components intended for transfusion be tested by a serologic test for HTLV–III. FDA also is proposing to amend §§ 640.14 and 640.53 editorially so that the language is consistent.

F. Testing Source Plasma

FDA is proposing to redesignate the existing text in § 640.67 as § 640.67(a) and add § 640.67(b). In § 640.67(b), FDA is proposing to require that Source Plasma be found nonreactive (nonpositive) by an approved serologic test for HTLV–III. Plasma centers would be required to perform a serologic test for HTLV–III on a blood sample collected from a plasma donor at each visit. A unit of Source Plasma testing positive by a serologic test for HTLV–III could not be used for further manufacture except as provided in proposed § 610.45(c). Under proposed § 610.45(c), FDA would permit the use of positive plasma only for purposes and under conditions specifically approved in writing by the Director, OBRR.

G. Labeling

FDA is proposing to add § 640.70(a)(11) to require that the statement "Nonreactive by serologic test for HTLV–III", or an equivalent statement, be included on the container label of Source Plasma. The proposed label statement would inform users of the Source Plasma that the product was properly tested and found nonreactive by a serologic test for HTLV–III. (See also paragraph II.A. of this preamble).

FDA recognizes that by the proposed effective date of the final rule, 30 days after its publication in the Federal Register, appropriately revised container labels may not be available at all plasma centers. Plasma centers may use means such as an ink stamp or stick-on label to include the information on the container label required by § 640.70(a)(11).

FDA believes that source plasma establishments will have revised printed container labels including the proposed statement in use within 1 year after the date of publication in the Federal Register of a final rule resulting from this proposal.

H. Manufacturing Responsibility

FDA is proposing to amend § 640.71 to permit establishments other than the establishment collecting the Source Plasma to perform the serologic test for HTLV–III. The proposed amendment is consistent with the intent of proposed § 610.45(b).

I. Records

FDA is proposing to amend § 640.72 to provide that negative test results for the serologic test for HTLV–III need not be kept in individual Source Plasma donor records if the test results are maintained elsewhere at the center where the donor's plasma was collected. This amendment will allow plasma centers to avoid duplicative and unnecessary recordkeeping.

III. Regulations Affected by the Proposed Amendments

In the following paragraphs, FDA discusses the effect of the proposed rule on existing requirements in the current good manufacturing practice for blood and blood components regulations at 21 CFR Part 606.

A. Facilities

Under § 606.40(a) (4) and (6), all blood establishments would be required to provide adequate space in a designated location to quarantine blood and blood components that were tested by a serologic test for HTLV–III and the test results were either questionable or reactive. Test results are questionable when, for example, the test results are close to the cut-off value, the control samples are out of range, or duplicate samples run at the same time have conflicting results. Such blood and blood components should remain in quarantine until test results show the blood and blood components to be nonreactive for antibody to HTLV–III. Under § 606.40(d)(2), blood establishments would be required to have adequate facilities to provide for the safe and sanitary disposal of blood and blood components positive by a serologic test for HTLV–III. FDA considers either autoclaving or incineration to be appropriate means for the safe and sanitary disposal of blood and blood components.

B. Standard Operating Procedures

Under § 606.100(b)(7), each blood establishment would be required to maintain on the premises and follow a written standard operating procedure describing the procedures for the serological test for HTLV–III, including followup procedures for any reactive tests.

C. Records

Under § 606.160(a) (1) and (2), blood establishments would be required to keep adequate records of the results of the serologic test for HTLV–III, including a record of the master lot number of the test kit and lot number of the HTLV–III reagent used for each test. The test results should be traceable to the individual donor and blood product.

Like all medical records, the test results should be recorded and stored in a manner to protect their continued confidentiality. Blood establishments should exercise particular care to assure confidentiality of positive test results. Disclosure of this information for other than medical or public health purposes could lead to serious consequences for the individual. Donor screening procedures should also be designed with safeguards to protect against unauthorized disclosure.

Under § 606.160(e), blood establishments would be required to maintain a permanent record identifying those donors whose blood is positive by a serologic test for HTLV–III so that in the future, blood and blood components from such individuals are not distributed. Whenever appropriate, donor deferral lists should be general, without indication of the reason for deferral. At the present time, there is inadequate evidence to determine how long an asymptomatic individual may carry HTLV–III virus in the blood. Until adequate data are available to show that infection with HTLV–III is self-limiting within a specific time period, individuals who have tested positive to a serologic test for HTLV–III should be permanently deferred from donating blood and blood components for routine purposes.

D. Donor Notification

At this time, FDA is not proposing specific regulations requiring the notification of a donor when the test for antibody to HTLV–III is repeatably positive. (A test is repeatably positive when upon retest using the licensed test system is repeatably reactive or upon retest using another technique, such as the Western blot, is positive for HTLV–III antibody.) However, FDA continues to support the recommendations of PHS for notification of donors, issued on January 11, 1985 (Ref. 19). Whatever procedures are selected, the blood establishment should assure that the donor is notified in as sensitive and informative a manner as possible.

IV. References

The following information has been placed in the Dockets Management Branch (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday. FDA intends to supplement the materials on file for this document as additional information, such as information related to licenses issued subsequent to this notice, becomes available.

1. FDA letter to all registered blood establishments dated December 14, 1984.

2. Gallo, R.C., et al., "Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV–III) from Patients with AIDS and at Risk for AIDS," *Science*, 224:500–503, 1984.

3. Sarngadharan, M.G., et al., "Antibodies Reactive with Human T-Lymphotropic Retroviruses (HTLV–III) in the Serum of

Patients with AIDS," *Science*, 244:506–508, 1984.

4. Groopman, J.E., et al., "HTLV–III in Saliva of People with AIDS-Related Complex and Healthy Homosexual Men at Risk for AIDS," *Science*, 226:447–449, 1984.

5. Zagury, D., et al., "HTLV–III in Cells Cultured from Semen of Two Patients with AIDS," *Science*, 226:449–451, 1984.

6. Melbye, M., et al., "Seroepidemiology of HTLV–III Antibody in Danish Homosexual Men: Prevalence, Transmission, and Disease Outcome," *British Medical Journal*, 289:573–575, 1984.

7. CDC, "Antibodies to a Retrovirus Etiologically Associated with Acquired Immunodeficiency Syndrome (AIDS) in Populations with Increased Incidences of the Syndrome," *Morbidity and Mortality Weekly Report*, 3:377–379, 1984.

8. Weiss, S.H., et al., "Screening Test for HTLV–III (AIDS Agent) Antibodies: Specificity, Sensitivity, and Applications," *Journal of the American Medical Association*, 253:221–225, 1985.

9. Goedert, J.J., et al., "Determinants of Retrovirus (HTLV–III) Antibody and Immunodeficiency Conditions in Homosexual Men," *Lancet*, 2:711–716, 1984.

10. Spira, T.J., et al., "Prevalence of Antibody to Lymphadenopathy-Associated Virus Among Drug-Detoxification Patients in New York," *New England Journal of Medicine*, 311:467–468, 1984.

11. Ramsey, R.B., et al., "Antibody to Lymphadenopathy-Associated Virus in Hemophiliacs with and without AIDS," *Lancet*, 2:397–398, 1984.

12. Tsoukas, C., et al., "Association of HTLV–III Antibodies and Cellular Immune Status of Hemophiliacs," *New England Journal of Medicine*, 311:1514–1515, 1984.

13. Harris, C.A., et al, "Antibodies to a Core Protein (p. 25) of Lymphadenopathy Associated Virus (LAV) and Immunodeficiency in Heterosexual Partners of AIDS Patients," presentation at 24th Interscience Conference on Microbial Agents and Chemotherapy, Washington, DC, 1984.

14. Levy, J.A., et al., "Isolation of Lymphocytopathic Retroviruses from San Francisco Patients with AIDS," *Science*, 225:840–842, 1984.

15. Safai, B., et al., "Seroepidemoliogical Studies of Human T-Lymphotropic Retrovirus Type III in Acquired Immunodeficiency Syndrome," *Lancet*, 1:1438–1440, 1984.

16. Laurence, J., et al., "Lymphadenopathy Associated Viral Antibody in AIDS," *New England Journal of Medicine*, 311:1269–1273, 1984.

17. Salahuddin, S.Z., et al., "HTLV–III in Symptom-Free Seronegative Persons," *Lancet*, 2:1418–1420, 1984.

18. Groopman, J.E., unpublished data.

19. CDC, "Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome," *Morbidity and Mortality Weekly Report*, 34:1–5, 1985.

20. FDA letter to all registered blood establishments, dated February 19, 1985.

21. FDA letter to all registered blood establishments, dated May 7, 1985.

22. PHS, "Testing Donors of Organs, Tissues, and Semen for Antibody to Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus," *Morbidity and Mortality Weekly Report*, 34:294, 1985.

23. Transcript of Feb. 22, 1985 meeting.

24. Transcript of July 31, 1985 public meeting (when available).

25. Data summaries supporting licensure of Human T-Lymphotropic Virus Type-III (when available).

V. Economic and Environmental Considerations

The agency has determined pursuant to 21 CFR 25.24(c)(10) (April 26, 1985; 50 FR 16636) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The agency has examined the economic impact of this proposed rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as specified in the Regulatory Flexibility Act (Pub. L. 96–354).

FDA concludes that a little over 2,000 establishments, about half of which are small businesses, would be affected by the proposed rule. FDA estimates that the proposed rule would require the performance of about 22 million serologic tests for HTLV-III antibody each year: 12 million tests on units of blood and 10 million tests on units of Source Plasma. The majority of the nation's blood banks and plasmapheresis centers, both large and small, are expected to perform the HTLV-III antibody test voluntarily even in the absence of this regulation. Officials of the American Blood Resources Association, the American Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers have stated that their organizations will voluntarily undertake to perform the test, even in the absence of a regulation requiring it. These organizations comprise the majority of the blood and plasma collections facilities in the United States. However, while some facilities that are not members of these organizations may not voluntarily undertake the testing program (in the absence of a regulation), their number is not known. Therefore, most of the costs of testing cannot be said to result from the regulation, and the agency has concluded that the regulation does not warrant either inclusion as a "major" rule as defined in Executive Order 12291 or a Regulatory Flexibility Analysis under Public Law 96–354. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch.

The major direct cost element, the cost of conducting the serological tests for the HTLV-III antibody, is expected initially to be about $3 per test for plasmapheresis centers and about $3 to $5 per test for blood banks. The expectations for testing cost estimates are based on information provided by plasmapheresis centers, blood banks, and independent testing laboratories. It should be noted that their expectations varied widely. For example, the American Red Cross indicated that the $3 to $5 cost figures may be low for their operations, citing their own estimates of from $5 to $10 per test, which may include costs not resulting from this regulation, such as overhead burden and independent HTLV-III tests for high risk populations. Current indications suggest that economies of scale for the HTLV-III antibody test operate to increase the test costs for small-volume testing centers. However, large-volume centers account for the majority of blood processed. Over time, the costs—particularly those at the higher end of this range—are expected to decrease as experience, increased use of computers and automation, and competition among producers of the test kits bring costs down. If these expected cost decreases indeed occur, and the average overall cost were on the order of $3, then the nationwide costs of processing the 12 million blood units and 7.5 million plasma donations collected annually would be somewhat less than $66 million. FDA estimates that at least 95 percent of blood establishments will initiate voluntarily a testing program for HTLV-III antibodies even in the absence of the proposed rule. Therefore, FDA estimates that direct costs of the proposed rule itself amount to a maximum of 5 percent of the total direct costs of the testing program.

Other direct costs of the testing program include the cost of retesting blood that has ambiguous or positive test results, the cost of disposing of and replacing discarded blood, and modest costs associated with labeling changes. It is expected that less than 1 percent of blood will have positive test results, but that an as-yet-unknown portion of these will be false positives. It is also expected that some negative test results (amount unknown) will be false negatives but, because false negative results due to laboratory error are believed to be quite rare, no retesting of negative results is required or planned at this time. Furthermore, indirect costs resulting from the tests may be substantial. Although indirect costs

cannot be quantified at this time, they include the costs of additional testing that may occur as part of the medical evaluation, notifying and counseling persons with positive test results, and the increased medical costs for followup of persons with positive test results. These medical costs will be partially or totally offset by the reduction in medical costs for those who are spared from AIDS as a result of the testing program. Another effect of the regulation will be to facilitate third-party payment for the incremental cost of performing the HTLV-III tests.

FDA cannot at this time quantify the benefits of the proposed rule, which are related primarily to the expected decrease in the risk of transmitting AIDS by transfusion. Much of this benefit would take place even in the absence of this regulation, since most of the blood industry is expected to institute HTLV-III antibody testing even without the regulation. The main benefits of the regulation are to standardize industry practices, thereby providing a more complete and timely assurance of the continued safety of the nation's blood supply.

The anticipated costs are insufficient to warrant designation of this proposal as a major rule under any of the criteria specified under section 1(b) of Executive order 12291 or to require a regulatory flexibility analysis. Accordingly, under section 605(b) of the Regulatory Flexibility Act, the Commissioner of Food and Drugs certifies that this rulemaking, if promulgated, will not have a significant economic impact on a substantial number of small entities. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch.

Sections 640.2(f) and 640.72(a)(2) of this proposed rule contain collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these collection of information requirements. Other organizations and individuals desiring to submit comments on the collections of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Bruce Artim.

In addition, the proposed rule would continue present collection of information requirements already submitted to OMB under section 3507 of the Paperwork Reduction Act (§§ 606.100 and 606.160, OMB control number 0910-0116).

VI. Comments

Interested persons may, on or before March 24, 1986, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm., 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. FDA is proposing this rule with a 30-day comment period to expedite publication of any final rule based on this proposal to decrease the risk of transmitting AIDS by blood transfusion and parenteral use of other products made from blood. Accordingly, good cause exists for a comment period of less than 60 days. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be indentified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m., and 4 p.m., Monday through Friday.

List of subjects

21 CFR Part 606

Blood, Laboratories.

21 CFR Part 610

Biologics, Labeling

21 CFR Part 640

Blood, Reporting requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Administrative Procedure Act, it is proposed that Parts 606, 610, and 640 be amended as follows:

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

1. The authority citation for Part 606 continues to read as follows:

Authority: Secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371) and the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 701–706)); 21 CFR 5.10.

2. In § 606.122 by revising paragraph (e) to read as follows:

§ 606.122 Instruction circular.

* * * * *

(e) Statements that the product was prepared from blood that was nonreactive when tested by a serologic test for HTLV–III and for hepatitis B surface antigen by FDA required tests and nonreactive when tested for syphilis by a serologic test for syphilis (STS).

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCT STANDARDS

3. The authority citation for Part 610 continues to read as follows:

Authority: Sec. 215, 58 Stat. 690 as amended; 42 U.S.C. 216, sec. 351, 58 Stat. 702 as amended, 42 U.S.C. 262; 21 CFR 5.10 and 5.11.

4. In Part 610 by adding § 610.45, to read as follows:

§ 610.45 HTLV–III requirements.

(a) *Testing requirements.* Each donation of human blood or blood components intended for use in preparing a product shall be tested by a serologic test for HTLV–III approved for such use by the Director, Office of Biologics Research and Review. In dire emergency situations, or as otherwise approved in writing by the Director, Office of Biologics Research and Review, blood and blood products may be issued before the results of the serologic test for HTLV–III are available, provided the test required by this paragraph is performed as soon as possible after issuance of the blood or blood product.

(b) *Testing responsibility.* The serologic test for HTLV–III shall be performed by the collection facility, by personnel of an establishment licensed to manufacture blood or blood derivatives under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or by a clinical laboratory which meets the standards of the Clinical Laboratory Improvement Act of 1967 (CLIA) (42 U.S.C. 263a), provided the establishment or clinical laboratory is qualified to perform the test.

(c) *Restrictions on use.* (1) Blood, plasma or other blood components that are positive to a serologic test for HTLV–III, or that were collected from a donor known to be positive to a serologic test for HTLV–III, shall not be shipped or used to prepare my product, including products not subject to licensure; except that such blood and blood components shall be shipped or used only for purposes and under conditions specifically approved in writing by the Director, Office of Biologics Research and Review.

(2) The restrictions on use contained in this paragraph shall not apply in the following cases:

(i) The distribution of blood, plasma, or serum samples, except when intended for use in the manufacture of a product;

(ii) The in-house use of blood and blood components for research purposes; or

(iii) The distribution of blood and blood components for research purposes, if not distributed by sale, barter or exchange.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

5. The authority citation for Part 640 continues to read as follows.

Authority: Sec. 215, 58 Stat. 690 as amended; 42 U.S.C. 216; sec. 351, 58 Stat. 702 as amended, 42 U.S.C. 262; 21 CFR 5.10 and 5.11.

6. In Part 640:

a. In § 640.2 by revising paragraph (f), to read as follows:

§ 640.2 General requirements.

* * * * *

(f) *Issue prior to determination of test results.* Notwithstanding the provisions of § 610.1 of this chapter, blood may be issued by the manufacturer on the request of a physician, hospital, or other medical facility before results of all tests prescribed in § 640.5, the test for hepatitis B surface antigen prescribed in § 610.40(a) of this chapter, and a serologic test for HTLV–III prescribed in § 610.45(a) of this chapter have been completed, where such issue is essential to allow time for transportation to assure arrival of the blood by the time it is needed for transfusion: *Provided,* That (1) the blood is shipped directly to such physician or medical facility, (2) the records of the manufacturer contain a full explanation of the need for such issue, and (3) the label on each container of such blood bears the information required by § 606.121(h) of this chapter.

b. In § 640.5 by adding paragraph (f), to read as follows:

§ 640.5 Testing the blood.

* * * * *

(f) *Serologic test for HTLV–III.* Whole Blood shall be tested by a serologic test for HTLV–III as prescribed in § 610.45 of this chapter.

c. By revising § 640.14, to read as follows:

§ 640.14 Testing the blood.

Blood from which Red Blood Cells are prepared shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

d. In § 640.23 by revising paragraph (a), to read as follows:

§ 640.23 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Platelets shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

* * * * *

e. In § 640.33 by revising paragraph (a), to read as follows:

§ 640.33 Testing the blood.

(a) Blood from which plasma is separated shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

* * * * *

f. In § 640.53 by revising paragraph (a), to read as follows:

§ 640.53 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Cryoprecipitated AHF shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a) (b), and (c).

* * * * *

g. By revising § 640.67, to read as follows:

§ 640.67 Laboratory tests.

(a) *Hepatitis B surface antigen.* Each unit of Source Plasma shall be nonreactive to a test for hepatitis B surface antigen as prescribed in §§ 610.40 and 610.41 of this chapter, except insofar as permitted in § 610.40(d) (2) and (3) of this chapter.

(b) *HTLV–III.* Each unit of Source Plasma shall be nonreactive by a serologic test for HTLV–III as prescribed in § 610.45 of this chapter, except as provided in § 610.45(c) of this chapter.

h. In § 640.70 by adding paragraph (a)(11), to read as follows:

§ 640.70 Labeling.

(a) * * *

(11) The statement "Nonreactive by serologic test for HTLV–III", or equivalent statement.

* * * * *

i. In § 640.71 by adding paragraph (a)(4), to read as follows:

§ 640.71 Manufacturing responsibility.

(a) * * *

(4) A serologic test for HTLV–III.

* * * * *

j. In § 640.72 by revising paragraph (a)(2), to read as follows:

§ 640.72 Records.

(a) * * *

(2) For each donor, a separate and complete record of all initial and periodic examinations, tests, laboratory data, interviews, etc., undertaken pursuant to §§ 640.63, 640.5, 640.66, and 640.67, except that negative test results for hepatitis B surface antigen, negative test results for the serologic test for HTLV–III, and the volume or weight of plasma withdrawn from a donor need not be kept on the individual donor record: *Provided,* That such information is maintained on the premises of the plasmaphereisis center where the donor's plasma has been collected.

* * * * *

Frank E. Young,

Commissioner of Food and Drugs.

Dated: January 27, 1986.

Otis R. Bowen,

Secretary of Health and Human Services.

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Friday
February 21, 1986

Part V

The President

Executive Order 12549—Debarment and Suspension

Office of Management and Budget

Guidelines for Nonprocurement Debarment and Suspension; Request for Comments

Federal Register
Vol. 51, No. 35
Friday February 21, 1986

Presidential Documents

Title 3—

The President

Executive Order 12549 of February 18, 1986

Debarment and Suspension

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to curb fraud, waste, and abuse in Federal programs, increase agency accountability, and ensure consistency among agency regulations concerning debarment and suspension of participants in Federal programs, it is hereby ordered that:

Section 1. (a) To the extent permitted by law and subject to the limitations in Section 1(c), Executive departments and agencies shall participate in a system for debarment and suspension from programs and activities involving Federal financial and nonfinancial assistance and benefits. Debarment or suspension of a participant in a program by one agency shall have government-wide effect.

(b) Activities covered by this Order include but are not limited to: grants, cooperative agreements, contracts of assistance, loans, and loan guarantees.

(c) This Order does not cover procurement programs and activities, direct Federal statutory entitlements or mandatory awards, direct awards to foreign governments or public international organizations, benefits to an individual as a personal entitlement, or Federal employment.

Sec. 2. To the extent permitted by law, Executive departments and agencies shall:

(a) Follow government-wide criteria and government-wide minimum due process procedures when they act to debar or suspend participants in affected programs.

(b) Send to the agency designated pursuant to Section 5 identifying information concerning debarred and suspended participants in affected programs, participants who have agreed to exclusion from participation, and participants declared ineligible under applicable law, including Executive Orders. This information shall be included in the list to be maintained pursuant to Section 5.

(c) Not allow a party to participate in any affected program if any Executive department or agency has debarred, suspended, or otherwise excluded (to the extent specified in the exclusion agreement) that party from participation in an affected program. An agency may grant an exception permitting a debarred, suspended, or excluded party to participate in a particular transaction upon a written determination by the agency head or authorized designee stating the reason(s) for deviating from this Presidential policy. However, I intend that exceptions to this policy should be granted only infrequently.

Sec. 3. Executive departments and agencies shall issue regulations governing their implementation of this Order that shall be consistent with the guidelines issued under Section 6. Proposed regulations shall be submitted to the Office of Management and Budget for review within four months of the date of the guidelines issued under Section 6. The Director of the Office of Management and Budget may return for reconsideration proposed regulations that the Director believes are inconsistent with the guidelines. Final regulations shall be published within twelve months of the date of the guidelines.

Sec. 4. There is hereby constituted the Interagency Committee on Debarment and Suspension, which shall monitor implementation of this Order. The

Committee shall consist of representatives of agencies designated by the Director of the Office of Management and Budget.

Sec. 5. The Director of the Office of Management and Budget shall designate a Federal agency to perform the following functions: maintain a current list of all individuals and organizations excluded from program participation under this Order, periodically distribute the list to Federal agencies, and study the feasibility of automating the list; coordinate with the lead agency responsible for government-wide debarment and suspension of contractors; chair the Interagency Committee established by Section 4; and report periodically to the Director on implementation of this Order, with the first report due within two years of the date of the Order.

Sec. 6. The Director of the Office of Management and Budget is authorized to issue guidelines to Executive departments and agencies that govern which programs and activities are covered by this Order, prescribe government-wide criteria and government-wide minimum due process procedures, and set forth other related details for the effective administration of the guidelines.

Sec. 7. The Director of the Office of Management and Budget shall report to the President within three years of the date of this Order on Federal agency compliance with the Order, including the number of exceptions made under Section 2(c), and shall make such recommendations as are appropriate further to curb fraud, waste, and abuse.

Ronald Reagan

THE WHITE HOUSE,
February 18, 1986.

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