donate blood or blood components for use as a component of a medical device or may donate blood or blood components in the preparation of Hepatitis B Immune Globulin (Human) provided their current donations test nonreactive when tested in accordance with § 610.40(a) and the donor is otherwise determined to be suitable.

(d) Donors with a reactive serologic test for syphilis need not be deferred if found negative by an approved specific treponemal test (confirmatory test for syphilis).

(e) Deferred donors may be found to be suitable as donors of blood or blood components by a method or process found acceptable for such purposes by the Food and Drug Administration.

8. Section 610.42 is added to subpart E to read as follows:

§ 610.42 Restrictions on use for further manufacture of in vitro diagnostic products.

In vitro diagnostic products manufactured from human blood or blood components found to be repeatedly reactive by a screening test performed in accordance with § 610.40(a) shall be labeled in accordance with § 809.10 of this chapter, and shall include a statement of warnings in the label indicating that the product was manufactured from a donation found to be repeatedly reactive by a screening test for evidence of infection due to the identified communicable disease agent.

9. Section 610.44 is added to subpart E to read as follows:

§ 610.44 Use of reference panels by manufacturers of test kits.

When available, a reference panel shall be obtained from the Center for Biologics Evaluation and Research or from a Food and Drug Administration designated source, and shall be used by the manufacturer to verify acceptable sensitivity and specificity of:

(a) Each lot of a test kit approved for use in testing donations of human blood and blood components for evidence of infection due to communicable disease agents listed in § 610.40(a); and

(b) Each lot of a human immunodeficiency virus (HIV) test approved for use in the diagnosis or monitoring of this communicable disease agent. A lot that is found to be not acceptable for sensitivity and specificity under § 610.44(a) and (b) shall not be released.

§ 610.45 [Removed]

10. Section 610.45 *Human Immunodeficiency Virus (HIV) requirements* is removed.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

11. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 640.2 [Amended]

12. Section 640.2 *General requirements* is amended by removing paragraph (f).

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

13. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 660.42 [Removed]

14. Section 660.42 *Reference panel* is removed.

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–21296 Filed 8–18–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 630

[Docket No. 98N–0607]

General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require blood and plasma establishments to notify donors of their deferral due to test results for communicable disease agents or failure to satisfy suitability criteria with the intent of reducing the risk of transmission of communicable disease through the use of blood, blood components, and blood derivatives. Under the proposed rule, blood and plasma establishments would notify the donors that they have been deferred and the reason for the deferral; provide information concerning appropriate medical followup and counseling; describe the types of donations the donors should not make in the future; and discuss the possibility that the donor may be found suitable in the future, where appropriate. FDA is issuing this rule as part of the agency's ''Blood Initiative'' in which FDA is reviewing and, when appropriate, revising its regulations, policies, guidance, and procedures related to blood and blood products, including blood derivatives.

DATES: Submit written comments by November 17, 1999. Submit written comments on the information collection provisions by September 20, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs (OMB), New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attention: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

For a variety of reasons discussed as follows, FDA has decided to comprehensively review and, as necessary, revise its regulations, policies, guidance, and procedures related to the licensing and regulation of blood products. In the **Federal Register** of June 3, 1994 (59 FR 28821 and 59 FR 28822, respectively), FDA issued two documents entitled ''Review of General Biologics and Licensing Regulations'' (Docket No. 94N–0066) and ''Review of Regulations for Blood Establishments and Blood Products'' (Docket No. 94N–0080). The documents announced the agency's intent to review biologics regulations (parts 600, 601, 606, 607, 610, 640 and 660 (21 CFR 600, 601, 606, 607, 610, 640 and 660)), and requested written comments from the public. Interested persons were given until August 17, 1994, to respond to the documents. In response to requests for additional time, FDA twice extended the comment period, as announced in the **Federal Register** of August 17, 1994

(59 FR 42193), and November 14, 1994 (59 FR 56448). In addition, FDA responded to requests for a public meeting to allow for the presentation of comments regarding the agency's intent to review the biologics regulations. On January 26, 1995, FDA held a public meeting to provide an opportunity for all interested individuals to present their comments and to assist the agency in determining whether the regulations should be revised, rescinded, or continued without change. Since the time of the regulation review, FDA has implemented a number of changes to its regulations and policies applicable to the general biologics and licensing regulations, some of which have applied to blood products as well as other biological products. (See, e.g., the final rules issued May 14, 1996 (61 FR 24313); August 1, 1996 (61 FR 40153); November 6, 1996 (61 FR 57328); July 24, 1997 (62 FR 39890); and October 15, 1997 (62 FR 53536)).

Because of the importance of a safe national blood supply, the U. S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations (the Subcommittee) and other groups such as the General Accounting Office (GAO), and the Institute of Medicine (IOM) have reviewed the agency's policies, practices, and regulations. Reports issued following the respective reviews made a number of recommendations as to how FDA might improve the biologics regulations, particularly as they apply to the continued safety of blood products. The relevant reports are: (1) ''Protecting the Nation's Blood Supply From Infectious Agents: The Need for New Standards to Meet New Threats,'' by the Subcommittee (August 2, 1996); (2) ''Blood Supply: FDA Oversight and Remaining Issues of Safety,'' by GAO (February 25, 1997); (3) ''Blood Supply: Transfusion-Associated Risk,'' by GAO (February 25, 1997); and (4) ''HIV and the Blood Supply: An Analysis of Crisis Decisionmaking,'' by IOM (July 13, 1995). These reports are on file with the Dockets Management Branch (address above) under the docket number given in the heading of this document.

FDA has reviewed these reports and agrees with the majority of the recommendations contained within them. However, rather than to only respond specifically to the recommendations from the Subcommittee, GAO, IOM, and the public, FDA has convened a number of internal task forces to review a variety of issues related to the regulation of blood and blood products, including how to most appropriately update the existing regulations applicable to blood and blood products. In the future, FDA intends to issue a number of blood-related rulemakings that various FDA task groups are currently preparing. FDA is not describing the specific recommendations it has received and the numerous objectives of the Blood Initiative in this document. Future rulemaking and other notices will describe and discuss specific recommendations and regulatory objectives.

II. Background on Notification of Deferred Donors

This rule is proposed in order to reduce the risk of infection due to communicable disease agents to blood product recipients and to individuals handling blood or blood products. The safety of the blood supply is enhanced when donors who may present significant risks of transmitting infectious disease, because of testing results indicating evidence of infection due to communicable disease agents or failure to satisfy suitability criteria associated with the prevention of certain communicable disease agents, are excluded from donating blood and blood components. FDA has issued regulations at parts 610 and 640 on donor testing and suitability in order to help assure the safety of blood products. The Public Health Service (PHS) and FDA, as part of PHS, also have periodically issued guidance on donor testing, suitability, deferral, and notification when new scientific developments warranted. This rule is also being proposed so that donors may be informed of their deferral and seek medical counseling or treatment, if appropriate. Additionally, such notification is expected to improve blood safety by preventing re-donation by individuals at risk for transmitting infectious disease. Also, precautions taken to minimize the risk of transmission by informed donors may reduce the spread of communicable diseases in the population.

FDA has taken a number of actions to provide for the notification of certain deferred donors. Described in the following paragraphs are some of the more significant actions and their impact on donor notification.

In 1983, PHS issued guidelines recommending that individuals at increased risk for Acquired Immune Deficiency Syndrome (AIDS) refrain from donating (Ref. 1).

In 1985, PHS issued guidelines concurrent with the approval of human immunodeficiency virus (HIV) antibody tests that donors testing repeatedly reactive in screening tests for human immunodeficiency virus, type 1 (HIV–1) be notified. In addition, PHS recommended that the donor be notified if other tests such as the Western blot were positive (Ref. 2).

In 1987, PHS recommended that a person be considered to have serologic evidence of HIV infection only after an enzyme immunoassay screening test was repeatedly reactive and another test such as Western blot had been performed to validate the results (Ref. 3). These recommendations have been updated periodically (Refs. 4 and 5) and extended to include notification of donors testing positive for antibody to human immunodeficiency virus, type 2 (HIV–2) (Ref. 6).

In its 1990 recommendations, FDA recommended to blood establishments that supplemental testing be performed prior to donor notification in its Memorandum to Blood Establishments: Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products.

In 1988, PHS recommended notification of donors who were confirmed positive for human T-lymphotropic virus, type I (HTLV–I) of their test results and that they had been deferred as a donor in Licensure of Screening Tests for Antibody to T-Lymphotropic Virus, Type I (Ref. 7).

In 1991, the Department of Health and Human Services (DHHS), in a PHS Inter-Agency Guideline, recommended notifying donors of the results of tests for hepatitis B surface antigen (HBsAg), antibody to hepatitis C virus (anti-HCV), alanine aminotransferase (ALT) and antibody to hepatitis B core (anti-HBc) in the Public Health Service Interagency Guideline for Screening Donors of Blood, Plasma, Organs, Tissue and Semen for Evidence of Hepatitis B and Hepatitis C (Ref. 8).

In the 1995 Guideline for Quality Assurance in Blood Establishments (60 FR 36290, July 14, 1995), FDA further identified donor notification and counseling as two of the five key elements of donor deferral.

The blood industry has adopted these recommendations as well as developed their own guidance on donor notification. Industry practice includes notifying donors who are permanently deferred due to positive test results for viral markers of their deferred status and providing recommendations for followup testing, counseling, and appropriate medical referral. In the past, however, FDA has not issued regulations on when a deferred donor should be notified. To further enhance the safety of the blood supply, FDA

believes that donors should be notified when they are deferred due to test results or donor suitability criteria. Accordingly, FDA is proposing to require notification of donors who are deferred for evidence of infection due to communicable disease agents as required under proposed § 610.41 and for failure to satisfy suitability criteria associated with the prevention of communicable diseases. The proposed rule would help assure consistency in the blood industry's notification practices, and would provide FDA with clear enforcement authority if compliance problems occur.

GAO, at the request of Congressman John Dingell, Ranking Minority Member, Committee on Commerce, House of Representatives, recently reviewed the FDA's ''layers of safety'' intended to help ensure the safety of blood products in order ''to identify issues that might threaten the nation's blood supply.'' In its report of February 1997 entitled ''Blood Supply: Transfusion Associated Risks,'' GAO concluded that ''the blood supply is safer today than at any time in recent history.'' Nevertheless, in an accompanying report (''Blood Supply: FDA Oversight and Remaining Issues of Safety''), GAO made several recommendations on improving the safety of our nation's blood supply. GAO recommended that ''(FDA) require blood facilities to notify all donors who are permanently deferred that they have been deferred and the medical reason they are deferred.'' Citing public health concerns, GAO further recommended that:

> * * * (N)otification be based on positive confirmatory tests for viral markers (for the viruses that have licensed confirmatory tests) and all other medical reasons that result in permanent deferral (for example, the intake of pituitary growth hormone). Notification should include the reason for the permanent deferral, possibilities for re-entry as a donor, and counseling or referral to the donor's physician (including, when pertinent, actions to be taken to minimize transmission of viruses to others).

In its response, DHHS generally agreed with the GAO recommendations. FDA believes the proposed donor notification rule would enhance blood safety by promoting self-exclusion of donors who may present significant risks to the blood supply. FDA believes that donors who are informed of and understand the significance of their deferred status are less likely to attempt to donate again, thus helping to assure a safer blood supply. Donor notification also would enhance the public health by informing donors, as appropriate, of the need to seek treatment and additional medical counseling. Such measures could benefit the health of the donor and also provide information needed to prevent further spread of infection.

III. The Impact of Other Proposed Rules

FDA intends to issue other proposed rules in conjunction with the proposed donor notification rule. FDA is proposing to revise the donor testing and deferral regulations in part 610, which apply to blood and blood components. The related proposed testing and deferral document is found elsewhere in this issue of the **Federal Register**. FDA also intends to issue in the near future a proposed rule to revise donor suitability requirements.

The related proposed testing and deferral rule would, among other things, add requirements to test blood and blood components for evidence of infection due to hepatitis C virus (HCV), HTLV–I, and HTLV–II, while retaining testing requirements for hepatitis B virus (HBV), HIV–1, and HIV–2. FDA intends that the proposed testing rule would replace the requirements currently found in §§ 610.40 through 610.45. The testing and deferral requirements for a serologic test for syphilis (i.e., evidence of infection due to *Treponema pallidum*) found in §§ 640.5 and 640.65 would remain in part 640. The related proposed testing and deferral rule also would add a requirement in proposed § 610.41 that, except in certain specified circumstances, donors testing repeatedly reactive for evidence of infection due to a communicable disease agent(s) listed in proposed § 610.40(a) be deferred from future donations of blood or blood components. In addition, donors testing reactive for a serologic test for syphilis would also be deferred except as provided in current § 640.65 or proposed § 610.41. Under the proposed donor notification rule, blood and plasma establishments would be required to notify donors who have been deferred under proposed § 610.41.

As mentioned previously, FDA also intends to propose to revise the donor suitability requirements for donors of blood and blood components. FDA intends to identify donor suitability criteria that would cause a donor to be deferred and thus trigger notification under the proposed donor notification document. Among those donor suitability criteria being considered are high risk behavior associated with the transmission of HIV, HBV, and HCV, such as past or present abuse of injectable drugs. A new section identifying donor suitability criteria will be designated in the final rule for donor notification.

IV. Legal Authority

FDA is proposing to issue this new rule under the authority of sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264 *et seq.*) and the provisions of the Federal Food, Drug, and Cosmetic Act (the act) that apply to drugs (21 U.S.C. 201 *et seq.*). Under section 361 of the PHS Act, FDA may make and enforce regulations necessary to prevent the introduction, transmission, and spread of communicable disease between the States or from foreign countries into the States (see Sec. I, 1966 Reorg. Plan No. 3 at 42 U.S.C. 202 for delegation of section 361 authority from the Surgeon General to the Secretary of the Department of Health and Human Services (Secretary); see 21 CFR 510.(a)(4) for delegation from the Secretary to the Food and Drug Administration). Intrastate transactions may also be regulated under section 361 of the PHS Act (see *Louisiana* v. *Mathew*, 427 F. Supp. 174, 176 (E.D.La. 1977)).

Notification of donors that they have been deferred and consequently should not attempt subsequent donations would help prevent unsafe units of blood or blood products from entering the blood supply. The proposed rule targets those donors who may present significant risks of infectious agents; thus, it works directly to prevent the introduction and spread of communicable disease. Moreover, the proposed rule is designed to help ensure that risks of transmitting infectious disease are excluded from the pool of eligible donors. FDA relies on a system of overlapping layers of safety to ensure the safety of the nation's blood products. One of the important layers of safety is the self-exclusion of donors because of high-risk behaviors associated with the risk of HIV, or hepatitis B and C, or signs and symptoms of AIDS and hepatitis. A second crucial layer of safety is the system of donor deferral registries designed to eliminate unsuitable donors from the donor population. Notification of donors who are deferred adds to the protection provided by donor deferral registries by making deferred donors aware that they should not attempt to donate again. Consequently, the screening of unsuitable donors provided by the registries is enhanced by the self-exclusion of donors who have been made aware of their status and the risks their donation may present to the blood supply.

The proposed notification rule also would protect the health of the deferred donor by assuring that the individual is

aware he or she may need further medical evaluation including testing, treatment, and counseling. As FDA has previously made clear ''(i)n an indirect but no less important manner, the requirements of donor protection assure * * * that there will be a continuous and healthy donor population'' (Additional Standards for Human Blood and Blood Products (41 FR 10762, March 12, 1976)).

FDA's license revocation regulations provide for the initiation of revocation proceedings, among other reasons, if the establishment or the product fails to conform to the standards in the license application or in the regulations designed to ensure the continued safety, purity, or potency of the product (§ 601.5). Section 351 of the PHS Act also provides for criminal penalties for violation of the laws governing biologics. Violations can be punishable by fines or imprisonment, or both.

The act also applies to biological products (42 U.S.C. 262(d)), as amended. Blood and blood components are considered drugs, as that term is defined in section 201(g)(1) of the act (21 U.S.C. 321(g)(1)) (see *United States* v. *Calise*, 217 F. Supp. 705 (S.D.N.Y. 1962)). Because blood and blood components are drugs under the act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the act. Under section 501(a)(2)(B) of the act, drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform with current good manufacturing practices (CGMP's) (21 U.S.C. 351(a)(2)(B)). Under the proposed donor notification rule, blood and plasma establishments would be required to develop standard operating procedures (SOP's) for notifying deferred donors. A blood or plasma establishment that failed to comply with donor notification procedures would violate CGMP's and, therefore, would be subject to the act's enforcement provisions.

V. Description of the Proposed Rule

FDA is proposing to create a new part 630, General Requirements for Blood, Blood Components, and Blood Derivatives. This part would include the following: (1) Consolidation of the criteria to be used when determining suitability of donors of human blood and blood components; (2) requirements for donor deferral from future donation when a donor fails to satisfy the suitability criteria; and (3) requirements for donor notification and the reason for their deferral due to donor test results or failure to satisfy suitability criteria. Donor suitability criteria and donor deferral are not the subject of this proposed rule. These proposed requirements will be addressed in a rulemaking to be published in the near future. As necessary, FDA may add other requirements applicable to blood products in the future. The focus of this proposed rulemaking would be to require donor notification when the donor is deferred due to testing results or failure to meet donor suitability criteria and to provide the reason for the deferral.

The proposed rule would require blood and plasma establishments to notify donors who are deferred in accordance with proposed § 610.41 or for failure to satisfy donor suitability criteria that they have been deferred as donors and the reason for their deferral. Deferred donors would be informed, as appropriate, that they should not donate blood or blood components in the future. Donors would also be informed about the need for additional counseling and medical evaluation, as appropriate. Under the proposed rule, blood and plasma establishments would be required to develop SOP's for deferring donors and notifying deferred donors. FDA is not proposing to require blood and plasma establishments to notify donors who the blood or plasma establishments may defer voluntarily for a variety of medical reasons beyond the requirements in proposed § 610.41 and donor suitability criteria associated with the prevention of communicable diseases. FDA recognizes that blood and plasma establishments would need to exercise medical judgment in determining which donors to defer voluntarily and whether to notify such donors. PHS and FDA may periodically issue recommendations on testing, deferral, and notification of donors who may be at risk of infectious disease.

Donors whose blood or blood components test repeatedly reactive for evidence of infection due to a communicable disease agent for which testing would be required by FDA under proposed § 610.40, or as specified for syphilis in current §§ 640.5 or 640.65, would be deferred in accordance with proposed § 610.41. Blood and plasma establishments would notify such deferred donors under the proposed notification rule that they have been deferred, and the reason for their deferral including their screening test results and the results of any approved supplemental (i.e., additional, more specific) tests that were performed. FDA currently requires that supplemental testing for both HIV–1 and HIV–2 antibodies be performed under § 610.46. PHS and FDA have recommended that HIV notification should occur after the results of the approved supplemental testing are available. Results of supplemental tests are useful in providing additional information for purposes of medical followup and counseling. Therefore, FDA is proposing that blood establishments attempt to obtain the results of supplemental testing proposed under § 610.40(c) prior to notifying donors of their deferral. FDA has included a maximum time period of 8 weeks to notify the donor. If notification occurs prior to receipt of the supplemental test results, blood establishments would be required to renotify the donors with the results of the supplemental testing.

Blood and plasma establishments would be required to notify deferred donors where appropriate, of the possibility for re-entry as donors of blood and blood components if they are found to be suitable using methods or processes approved by FDA in accordance with proposed § 610.41 or current § 640.65, provided that the donor meets all other requirements.

Under § 610.40 of the proposed testing rule, blood and plasma establishments would be required to test blood and blood components, including autologous donations, for evidence of infection due to HIV–1, HIV–2, HBV, HCV, HTLV–I, and HTLV–II using FDA approved tests. Donors whose donations test repeatedly reactive for evidence of those agents required under proposed § 610.40(a) or for syphilis under current §§ 640.5 and 640.65 would be deferred in accordance with proposed § 610.41. This proposed donor notification rule would require that blood and plasma establishments notify the deferred donor of their deferral and of their test results.

In the related proposed § 610.41, FDA is proposing several exceptions to donor deferral that also have an impact on donor notification. Autologous donors testing repeatedly reactive for communicable disease agents would not be deferred. Blood establishments would not be required under this proposed rule to notify autologous donors who test repeatedly reactive for communicable disease agents under proposed § 610.40(a). Nevertheless, FDA recommends that blood establishments notify autologous donors of repeatedly reactive test results and supplemental test results, when applicable, for the purpose of medical followup and counseling. FDA specifically is requesting comments on whether to require notification of autologous donors of repeatedly reactive and supplemental test results even though such donors would not be deferred.

In the related proposed § 610.41(a), donors who test repeatedly reactive for HTLV, types I and II, or anti-HBc on only one occasion, would be permitted to donate again without being deferred from further donation unless there is further testing using an approved supplemental (additional, more specific) test. Should licensed supplemental tests for HTLV, types I and II be approved, donors would be required to be deferred after only a single repeatedly reactive donation similar to most other screening tests. It is FDA's expectation that donor re-entry algorithms would become feasible at that time. However, until such time, upon testing repeatedly reactive a second time for HTLV, types I and II or anti-HBc, the donor would be deferred. Blood establishments would be required to notify donors that they have been deferred from donations of Whole Blood, and transfusable components (including Plasma) only after they had tested repeatedly reactive a second time for HTLV, types I and II or anti-HBc. FDA specifically requests comments on whether to notify donors who test repeatedly reactive for HTLV, types I and II or anti-HBc on only one occasion or to wait to notify donors upon testing repeatedly reactive the second time. Upon the availability of an approved supplemental (additional, more specific) test, a repeatedly reactive donor would be deferred after a single repeatedly reactive donation. At such time, blood establishments would notify donors of the test results of both the approved screening and supplemental tests. As appropriate, blood establishments would notify such deferred donors that they may be eligible for re-entry if determined to be suitable by a method or process approved by FDA in accordance with proposed § 610.41.

In related § 610.41(b), FDA is proposing to except from deferral donors testing repeatedly reactive for HTLV, types I and II, or anti-HBc as donors of Source Plasma. However, the agency is requesting comments in the proposed rule ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (hereinafter the ''proposed rule on donor testing'') on permitting such donors to donate Source Plasma to be used in the manufacture of plasma derivatives as it relates to the exposure to other possible risks, such as through the association of HTLV infection with abuse of intravenous drugs. The agency also includes in the proposed rule on donor testing a discussion on the risk of transmitting HTLV, types I and II.

Related proposed § 610.41(c)(1) would permit deferred donors to donate blood and blood components used in accordance with proposed § 610.40(f). In related proposed § 610.40(f), the agency would require that blood and blood components that test repeatedly reactive when screened for evidence of infection due to communicable disease agents listed in proposed § 610.40(a) would not be shipped or used except for autologous use or for purposes or under conditions approved in writing by FDA. Blood and plasma establishments that collect blood or blood components under conditions approved under proposed § 610.40(f)(2)(ii) or current § 640.65 could notify donors deferred under proposed § 610.41 or current § 640.65 that they would be eligible to donate blood or blood components, as appropriate, for use as a component of an in vitro device or for other approved uses.

In related § 610.41(c)(2), the agency is proposing to restrict the use of blood or blood components from donors showing previous evidence of infection due to hepatitis B virus when tested in accordance with proposed § 610.40(a) and (c). Such blood and blood components may be approved for use only as a source of antibody to hepatitis B surface antigen for the preparation of Hepatitis B Immune Globulin (Human) or as a component of a medical device. Donors with previous evidence of infection with hepatitis B when tested in accordance with proposed § 610.40(a) and (c) may serve as donors of a component of a medical device or as donors of Source Plasma for use as a source of antibody to hepatitis B surface antigen for the preparation of Hepatitis B Immune Globulin (Human). In the proposed rule on donor testing, the agency has requested comments on the use of vaccinated donors for HBV as an alternative to using donors previously showing evidence of infection due to hepatitis B virus in the preparation of Hepatitis B Immune Globulin (Human) provided their current donations test nonreactive when tested in accordance with proposed § 610.40(a) and the donor is otherwise determined to be suitable. Blood and plasma establishments that are approved to collect Source Plasma from such donors under proposed § 610.40(f) could notify deferred donors that they may donate for such purposes.

In related proposed § 610.41, the agency is proposing to defer donors who test reactive for a serologic test for syphilis except as provided under current § 640.65. In related proposed § 610.41(d), the agency would exempt from deferral donors who test reactive on a serologic test for syphilis provided the donor is found negative by an approved specific treponemal test (confirmatory test for syphilis). Blood and plasma establishments would notify all other donors who test reactive for evidence of syphilis that they have been deferred and of the results of tests including the result of the approved specific treponemal tests. However, as FDA has noted in the preamble to the related proposed rule on donor testing, there is ongoing debate in the scientific community as to the continuing need for a testing requirement for the serological test for syphilis. Therefore, the proposal to defer donors who test reactive for syphilis is subject to change pending the outcome of the request for comments on the value of donor testing for syphilis in the proposed rule on donor testing.

The proposed rule also would require blood and plasma establishments to notify donors who have been deferred because of donor suitability criteria. FDA intends to create in future rulemaking a new section identifying certain donor suitability criteria which are intended to reduce the risk of communicable disease agents that would result in deferral of the donor and require donor notification. Among those donor suitability criteria being considered are high risk behavior associated with the transmission of HIV, HBV, and HCV, such as past or present abuse of injectable drugs. Blood and plasma establishments would notify deferred donors of their deferral and advise them to seek further testing or medical counseling, as appropriate.

Under the proposed rule, blood and plasma establishments would be required to provide information to deferred donors concerning appropriate medical followup and counseling. FDA currently recommends that this information include disease associations and possible modes of transmission as well as actions to be taken to minimize the risk of transmission. FDA believes that such information also would include referral to their own physician, or, where appropriate, the location of public health clinics as well as alternative testing and counseling centers. Blood and plasma establishments should consult current PHS Guidelines and FDA recommendations for more detailed recommendations on the content of donor notification.

A. Timeframe for Notification.

Under § 630.6(c) of the proposed rule, blood and plasma establishments would be required to notify donors within 8 weeks after determining that the donor should be deferred. In many instances

arising under the proposed rule, blood and plasma establishments would be able to fulfill the notification requirements onsite. For example, a donor who is deferred because of donor suitability criteria can be notified at the time of the donor interview or at the first return visit after the information is available, if within 8 weeks. Blood and plasma establishments would be required to have SOP's addressing donor deferral and notification and keep documentation on all deferrals as well as any resulting notification. Some blood and plasma establishments may notify deferred donors by registered mail, return receipt; or may choose to request that the donor return for direct donor notification, so long as notification of deferral occurred within the 8-week period. FDA requests comments on (1) methods of notification that would help assure adequate donor confidentiality and (2) the current application and sufficiency of Federal, State, and local laws that protect the privacy of the individual being notified. FDA believes that at least three attempts should be made within an 8-week period. In all cases, blood and plasma establishments should document their attempts to notify donors and maintain a record of these attempts or of the basis for discontinuing the effort to notify deferred donors.

B. Other Requirements.

Donor notification should be conducted by trained personnel in accordance with the requirements in § 606.20. Blood and plasma establishments would be required to revise their SOP's to include procedures for notification of deferred donors. For the purposes of notification under the proposed rule, blood and plasma establishments would be required to maintain records of the donor's permanent address. Donors should provide proof of a permanent, fixed address. Individuals who do not have evidence of a current address or who merely provide an address of a known or obviously transient nature should not be accepted as donors.

VI. Analysis of Impacts and Initial Regulatory Flexibility Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is 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 Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

OMB has determined that the proposed rule is is a significant regulatory action as defined by the Executive Order and so is subject to review. Because the rule does not impose any mandates on State, local, or tribal governments, or the private sector, that will result in any 1 year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandate Reform Act.

The Regulatory Flexibility Act requires agencies to prepare a Regulatory Flexibility Analysis for each rule unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained in the following sections of this document, the proposed rule is not expected to have a significant economic impact on a substantial number of small business entities because donor deferral and notification are considered usual and customary business for the affected entities.

A. Objectives and Basis of the Proposed Action

As discussed previously, FDA is considering the proposed action for the purpose of reducing the risk of infection due to communicable disease agents to blood recipients and to individuals handling blood or blood products. The safety of the nation's blood supply is enhanced when donors whose test results indicate evidence of infection due to communicable disease agents or fail to satisfy suitability criteria associated with the prevention of certain communicable disease agents are excluded from donating blood and blood components. Once donors are deferred from donation, such donors would be informed of their deferral and the reason, and advised to seek medical counseling or treatment, as appropriate. Public health would be protected not only by deferring the donor from future donations and preventing the transmission of communicable disease agents through transfusion, but also by counseling the donor in precautions to minimize the risk of transmitting the disease to others in daily life.

This action is taken under the authority of sections 351 and 361 of the PHS Act and section 501 of the act to prevent the introduction, transmission, and spread of communicable disease, and to ensure that methods used in manufacturing conform with CGMP's. Failure to comply with donor notification procedures would violate CGMP's and, therefore, would be subject to the act's enforcement provisions. FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with the proposed rule.

B. Nature of the Impact

The proposed rule requires that blood establishments notify deferred donors of their deferral based on either suitability criteria included in the donor screening interview or because of the results of testing for evidence of infection due to disease agents including HIV, HTLV, hepatitis B, or hepatitis C. Under the proposed rule, the donor must be notified that he or she has been deferred, and the reason for deferral. The deferred donor must also be notified of the types of blood or blood components that should not be donated in the future. The notification must also include the results of tests for evidence of infection due to communicable disease including supplemental test results, information concerning appropriate medical followup and counseling, and when applicable, the possibility that the donor may be found suitable for future donations. The donor notification process must include three attempts of notification, completed within 8 weeks of the determination of the donor deferral. In order to implement this notification process, the proposed rule also requires that blood establishments obtain a permanent address for each prospective donor. The establishment must also maintain records of its attempts to notify a deferred donor within the prescribed timeframe.

C. Type and Number of Entities Affected

The proposed deferred donor notification requirements will affect all blood and plasma establishments that collect blood and blood components from allogeneic donors. FDA's Office of Blood Research and Review (OBRR) has record of 2,801 registered blood and plasma establishments, including 487

plasma centers and 2,314 blood centers. The American Association of Blood Banks (AABB) estimates that approximately 14 million blood donations are collected annually. Allogeneic blood donations have recently accounted for an estimated 87.2 percent of that total (Ref. 9). In 1997, GAO estimated that approximately 12 million donations of source plasma were collected by plasma centers (Ref. 10).

D. Estimated Impact of Proposed Requirements for Deferred Donor Notification

The proposed rule is expected to have a minor net impact on blood establishments because the blood industry has already generally implemented deferred donor notification; virtually all establishments include this process within current operational guidelines. FDA expects that the primary impacts of the proposed rule will include a one-time review effort at each facility and a more extensive notification process at those facilities that currently perform deferred donor notification over a longer timeframe or with fewer followup attempts than specified in the rule.

The one-time effort to review and modify current SOP's is expected to vary among establishments depending on the extensiveness of a facility's current protocols for deferred donor notification. For establishments that already keep required donor information and perform the level of notification effort specified by the rule, FDA estimates that it would take approximately 4 hours of staff time to reconcile the proposed regulations against the facility's current standards. This process could be performed by a technical specialist who acts as a regulatory reviewer or manager of quality assurance. Based on the total average hourly compensation of $25.67 for professional specialty and technical occupations in the health services industry, as reported by the Bureau of Labor Statistics for March 1997, the cost would be approximately $103 per facility. For establishments that already perform donor deferral notification but information provided to deferred donors or other aspects of the notification process are not the same as specified in the proposed rule, FDA assumes that approximately 24 hours of staff time would be required to align current SOP's and donor recordkeeping with the provisions of the rule. The cost in this case would be approximately $616 per facility. FDA does not have the data to estimate the percentage of facilities that will require a minimal effort versus a more involved review of SOP's; however, it is expected that many facilities have SOP's and recordkeeping standards that are consistent with the rule. Assuming a minimal review is needed at two-thirds of the currently operating establishments, and a more extensive review is conducted by the others, the total one-time cost for the blood and plasma industries is estimated to be $762,158.

The yearly increase in cost is based on the ongoing notification of deferred donors. FDA assumes that all donors deferred based on the screening interview can be notified onsite at the time of deferral, and provided with the proposed information. FDA assumes that this will introduce no new costs for the blood and plasma establishments. The cost of notifying donors deferred on the basis of blood test findings is based on a proportional extrapolation of the number of donors who would test repeatedly reactive for evidence of infection in tests for HIV, HTLV, HBV, or HCV, and have positive findings in supplemental testing. Assuming a prevalence rate of 121.9 per 100,000 for viral markers for HIV, HTLV, HBV, or HCV among prospective donors (Ref. 11), that approximately 80 percent of donations are made by repeat donors [1], that repeat donors average two donated units per year [2], and that first time donors contribute one unit, an estimated 8,887 deferred blood donors and 8,861 plasma donors (including first time and repeat donors) would be identified each year.

FDA assumes that all facilities currently make at least one notification attempt for all deferred donors. However, the percentage of facilities that currently make up to three documented attempts within an 8-week period is not known. FDA has therefore estimated the economic impact for two scenarios in which the cost of compliance is based on the assumption that two additional notification attempts are needed, and these notifications are made via registered mail with a return receipt requested, at a cost of $12.54 [3] per notified donor. Under the first scenario, FDA assumes half of deferred donors are currently notified through a process like the one specified in the proposed rule. In this case, the cost of compliance, based on the cost of up to two additional notifications to the remaining half of the estimated deferred donors totals $55,719 for the blood industry, and an estimated $55,557 for the plasma industry. Under the second scenario, FDA considers that only one-quarter of deferred donors are currently receiving up to three notification attempts. Under this scenario, the cost of up to two additional notifications to the remaining three-quarters of the estimated deferred donors totals $83,578 for the blood industry, and an estimated $83,335 for the plasma industry. Thus, the ongoing notification costs for the blood and plasma industries combined are estimated to range from $111,276 to $166,913 per year.

E. Expected Benefits of the Proposed Rule

As described in the preamble to this rule, notification of donors that they have been deferred and consequently should not attempt subsequent donations will help prevent unsafe units of blood or blood products from entering the blood supply. Notification of donors who are deferred and can self-defer in the future thus adds to the protection provided by donor deferral registries. In FDA's proposed rule on donor testing found elsewhere in this issue of the **Federal Register**, the agency provides an extensive discussion of the benefits of reducing public exposure to the risks of these infectious diseases. FDA refers the reader to this discussion of the significant public health benefits of minimizing patients' risk of being unwittingly exposed to infection with HIV, HTLV, hepatitis B, and hepatitis C.

F. Small Entity Impact

The proposed rule is not expected to have a significant impact on a substantial number of small entities, however, the impact on blood and plasma establishments that qualify as small entities is uncertain. FDA has therefore prepared an initial regulatory flexibility analysis. The blood and plasma establishments affected by the proposed rule are included under the major standard industrial code (SIC) group 80 for providers of health services. According to section 601 of the Regulatory Flexibility Act of 1980, the term ''small entity'' encompasses the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' According to the Small Business Administration (SBA), a small business within the blood industry is an

[1] This percentage is based on American Red Cross estimates based on donations between January 1996 and June 1997.

[2] The estimate of an average of two donations per year for repeat blood donors is based on the Center for Disease Control's (CDC's) analysis of blood donations prepared for HCV lookback.

[3] This estimate is based on two mailings, at a cost of $6.27 each. This cost includes $.32 first class postage plus $4.85 fee for registered mail without insurance, plus $1.10 fee for return receipt requested at the time of mailing showing whom, signature, date and addressee's address (if different) source: USPS 1997 Postal Rates @ ''www.usps.gov/consumer''.

enterprise with less than $5 million in annual receipts. A small organization is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field. A ''small governmental jurisdiction'' generally means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.

As noted in the foregoing analysis, the proposed rule is expected to have some cost impact on both plasma and blood collection centers. FDA has registered a total of 487 plasma collection facilities. Of that total, the General Accounting Office (GAO) (Ref. 12) has identified approximately 370 for-profit plasma collection centers that primarily collect paid plasma donations. The remaining 100 or so plasma collection facilities function within blood collection centers with volunteer donors, that are either operated by the American Red Cross, or are independently operated. The vast majority of collected source plasma is processed by four companies: Alpha Therapeutic Corp., Baxter Healthcare Corp., Bayer Corp., and Centeon LLC.

FDA estimates that approximately 90 percent of these 370 paid plasma collection centers are owned by companies that operate a number of centers and have annual receipts in excess of $5 million per year. The remaining 10 percent, or about 37 paid plasma collection centers, may qualify as small business establishments. Of the 100 or so volunteer plasma collection facilities within blood collection centers, the independently operated, not-for-profit blood collection centers would likely qualify as small entities. The potential impact on plasma collection facilities will be a function of the number of donors and the viral marker rates among donors at their facility. The net impact on these facilities, however, is expected to be minor. For example, under cost scenario 1, if the additional yearly cost of $55,557 were evenly distributed across all 487 registered facilities, this would translate to an added cost of $114 per facility per year. Under scenario 2, the added cost per facility would be approximately $171 per year.

The impact on blood collection facilities that qualify as small entities is also uncertain, although it is not expected to be significant. The blood collection facilities that are independent and not-for-profit organizations may qualify as small entities regardless of the size of their operations. The analysis that follows, however, considers the smaller blood collection facilities, because they are expected to experience the greater cost impact. According to the 1996 directory of the AABB, 34 regional and community blood centers have annual revenues of less than $5 million; and each collect no more than 30,000 donations per year. Because of the pre-existing practice of deferred donor notification at these facilities, and the relatively small number of donors that FDA estimates will be deferred based on blood test findings, the impact on these small facilities is expected to be minor. Based on FDA's calculations, facilities with 30,000 donations or less per year would identify about 22 deferred donors per year through blood testing. At a cost of $6.27 per notification via registered mail with a return receipt, if all facilities currently need to make two additional notification attempts under this rule, there would be an average small facility notification cost of $278 (22 x $12.54) per year. Because the estimated one-time cost for the review and revision of current deferral notification SOP's equaled $271 (2/3 x $103 + 1/3 x $616), or about $39 when annualized over a 10-year payment period at a 7-percent interest rate, the average annualized cost impact for the smaller collection centers would be about $317 ($278 + $39), or roughly $0.01 per donation, assuming approximately 30,000 donations per year. It should be noted that blood collection centers that collect both blood and source plasma will not experience a ''double'' impact, because the same donor pool and donations are used for production of the center's blood and plasma products.

The types of professional staff and skills required to perform the required tasks were described in section VI.D of this document. FDA is confident that the tasks specified in the proposed rule can be readily performed by the type of staff already employed at affected blood and plasma establishments.

To alleviate the impact on small entities while continuing to protect public health, the agency is proposing to recommend, but not require, that autologous donors be notified, if they test repeatedly reactive for evidence of infection; FDA also does not require that these donors be deferred. To minimize facility notification efforts while achieving the public health objectives, FDA proposes that notification should not occur until after the results of the approved supplemental testing are available. The proposed regulations are thus expected to help enhance both public health and public confidence in the safety of the blood and plasma supply, while imposing minimum burden on manufacturers.

As an alternative to this proposal, FDA has considered not requiring donor notification of deferral from future donation due to communicable disease testing or failure to satisfy suitability criteria associated with the prevention of communicable disease because it is viewed by many as medical practice. However, the agency has rejected this alternative for the following reason. After a lengthy period of time during which the agency published recommendations to establishments on notifying donors of deferral, inconsistency pertaining to information and counseling provided to the deferred donor has been demonstrated among the establishments. Notification of donor deferral has become a public health issue because donors who are not fully informed of their deferral status due to communicable disease testing or failure to meet suitability criteria associated with the prevention of communicable disease may not take precautions to minimize the transmission of communicable disease to others and may not recognize the importance of not attempting to donate blood or blood components in the future.

VII. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in this section of this document with an estimate of the annual burden. Included in this estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA 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 proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors.

Description: FDA is proposing requirements for the donor notification process which are intended to prevent further donations from donors who have been deferred for positive test results for evidence of communicable disease agent(s) or for failing to meet the donor suitability criteria intended to reduce the risk of communicable disease agents prior to collection. When a donor is deferred for failing to meet suitability criteria associated with communicable disease agents prior to collection, he or she would be advised not to donate now or in the future and would be provided with information regarding the need for medical followup and counseling. When test results for communicable disease agents are finished, establishment personnel would be required to make at least three attempts to notify donors with positive supplemental (additional, more specific) test results that they are deferred and should have medical followup and counseling. The revisions would require blood and plasma establishments to develop SOP's for deferring donors and for notifying deferred donors and to maintain their permanent address, outline the information that is to be provided to a deferred donor, and to notify deferred donors of positive test results for evidence of infection by communicable disease agent(s) within 8 weeks of the donation initiating deferral, or at their first return visit, whichever is earlier. FDA is proposing these new requirements to help ensure the nation's blood supply is safe by excluding donors who may present significant risks from donating in the future as well as enhancing the public health by assuring that those donors who have been deferred are advised to seek treatment and counseling.

Description of Respondents: Manufacturers of blood, blood components, and blood derivatives.

There are an estimated 2,800 FDA registered blood and Source Plasma collection facilities in the United States that collect approximately 27,000,000 units of Whole Blood and Source Plasma annually. There are approximately 8 million donors of Whole Blood and 1.5 million donors of plasma for a total of 9.5 million donors per year. From such information as is available to FDA, the agency estimates that approximately 1.2 percent of persons who come to donate annually are deferred prior to donating because of disqualifying answers to the medical history and behavior questionnaire. In addition to the 9.5 million donors per year there would be approximately 115,385 potential donors deferred from donating. It is the customary and usual practice of virtually all registered establishments to explain to a donor why he or she is deferred and excluded from donating. Based on such information as is available to FDA, the agency estimates that currently two-thirds of registered establishments voluntarily provide additional information and counseling to a deferred donor. Consequently, only one-third or 933 collection facilities would have additional burden related to this proposed rule. Some industry contacts estimated that it takes on average approximately 5 minutes to provide the deferred donor with the appropriate medical health information. FDA estimates that currently 95 percent of the industry that collects 98 percent of the blood and blood components have voluntarily established SOP's for notifying donors who have repeatedly reactive test results that also are positive by supplemental tests for HIV, HBV, or HCV (the number of donors who test and confirm positive for HTLV is so small that this was not included in the estimate). FDA estimates based on 9.5 million donors annually and the viral marker incidence rates for HIV, HBV, and HCV, that 49,591 donors would be deferred annually due to test results. Consequently, 5 percent (140) of the industry collecting 2 percent (992) of the deferred donors would experience new burden related to this proposed rule. FDA estimates on the average it may take 15 minutes to allow for up to three attempts to contact a donor and request that they return for counseling which may take another 15 minutes for a total of 0.5 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
630.6(a) and (b)[2]	933	41	38,462	.08	3,077
630.6(a), (b), and (c)[3]	140	7	992	0.5	496
TOTAL					4,069

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

[2] Potential donors deferred prior to donation. The number of potential donors deferred annually prior to donation based on failure to meet suitability criteria associated with communicable disease agents is 115,385. Providing information on medical followup and counseling to these deferred donors is estimated to be new burden for approximately one-third of the registered blood and plasma collection facilities.

[3] Donors deferred post donation due to test results. Providing information on medical followup and counseling to donors deferred due to test results may be new burden for approximately 5 percent of the industry collecting from 2 percent of such deferred donors. One hundred and forty represents 5 percent of the 2,800 registered establishments and 992 represents 2 percent of the estimated 49,591 donors deferred annually due to test results.

TABLE 2.— ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)(20)	2,800	1	2,800	2	5,600
606.160(b)(1)(ix)[2]	2,800	59	164,976	3	8,400
606.160(b)(1)(x)[3]	2,800	9,643	27,000,000	0	0
TOTAL					14,000

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

[2] FDA estimates that annually 115,385 potential donors are deferred prior to donation and 49,591 donors are deferred due to test results. Recording the notification of each deferred donor is estimated to require between 2 and 5 minutes (3 minutes on average).

[3] Recording the donor's permanent address is customary and usual practice in the industry and is not new or additional burden.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for review of the information collection provisions. Interested persons are requested to submit written comments regarding information collection by September 20, 1999, to the Office of Information and Regulatory Affairs, OMB (address above), Attention: Desk Officer for FDA.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.31(j) that this action is of a type that not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Request for Comments and Effective Date

Interested persons may, on or before November 17, 1999, submit to the Docket Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified 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. FDA is proposing that any final rule that may issue based upon this proposed rule become effective 180 days after its date of publication in the **Federal Register**.

X. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. *Morbidity and Mortality Weekly Report*, vol. 32, pp. 101–103, March 4, 1983.

2. *Morbidity and Mortality Weekly Report*, vol. 34, pp. 1–5, January 11, 1985.

3. *Morbidity and Mortality Weekly Report*, vol. 36, pp. 509–515, August 14, 1987.

4. *Morbidity and Mortality Weekly Report*, vol. 36, pp. 833–840, January 8, 1988.

5. *Morbidity and Mortality Weekly Report*, vol. 38 (No. S–7), July 21, 1989.

6. *Morbidity and Mortality Weekly Report*, vol. 41 (No. RR–2), pp. 1–9, February 28, 1992.

7. *Morbidity and Mortality Weekly Report*, vol. 37, pp. 736–747, December 9, 1988.

8. *Morbidity and Mortality Weekly Report*, vol. 40 (No. RR–4), pp. 1–17, April 19, 1991.

9. Wallace, E. L., W. H. Churchill, D. M. Surgenor, J. An, G. Cho, S. McGurk, and L. Murphy, ''Collection and Transfusion of Blood and Blood Components in the United States, 1992,'' *Transfusion*, 1995; vol. 35, No. 10, pp. 802–812.

10. General Accounting Office, ''Blood Safety: Enhancing Safeguards Would Strengthen the Nation's Blood Supply,'' GAO–HEHS–97–143, June 1997.

11. Glynn, S. A., G. B. Schreiber, M. P. Busch, S. H. Kleinman, A. E. Williams, C. C. Nass, H. E. Ownby, and J. W. Smith, for the Retrovirus Epidemiology Donor Study, ''Demographic Characteristics, Unreported Risk Behaviors, and the Prevalence and Incidence of Viral Infections: A Comparison of Apheresis and Whole-Blood Donors,'' *Transfusion*, April 1998, vol. 38, pp. 350–358.

12. General Accounting Office, ''Blood Plasma Safety: Plasma Product Risks Are Low if Good Manufacturing Practices Are Followed,'' GAO–HEHS–98–205, September 1998.

Lists of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 630

Biologics, Blood, 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, it is proposed that 21 CFR Chapter I be 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: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371,374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.100 is amended by adding paragraph (b)(20) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) * * *

(20) Procedures for donor deferral as prescribed in § 610.41 of this chapter and donor notification, including procedures for the appropriate followup if the initial attempt at notification fails, as prescribed in § 630.6 of this chapter.

* * * * *

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

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(ix) Notification of deferred donors, including appropriate followup if the initial attempt at notification fails.

(x) To facilitate the notification of deferred donor, the donor's permanent address.

* * * * *

4. Part 630 is added to read as follows:

PART 630—GENERAL REQUIREMENTS FOR BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES

Sec.

630.6 Donor notification.

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371; 42 U.S.C. 216, 262, 263.

§ 630.6 Donor notification.

(a) An establishment that collects blood or blood components shall notify donors who have been deferred based on results of tests for evidence of infection with a communicable disease agent as required by § 610.41 of this chapter or based on deferral for suitability criteria. Blood establishments shall attempt to obtain the results of supplemental testing required under § 610.40(c) of this chapter prior to notifying donors of their deferral. If notification occurs prior to receipt of such results, blood establishments shall renotify donors of the results of the supplemental testing. Blood establishments shall notify donors as described in paragraph (b) of this section.

(b) The notification shall provide the following information to a donor who has been deferred from donating as described in paragraph (a) of this section:

(1) That the donor has been deferred and the reason for deferral;

(2) The types of donations of blood or blood components which the donor should not donate in the future;

(3) Where applicable, the results of tests for evidence of infection due to communicable disease agent(s), that were a basis for deferral under § 610.41 of this chapter, including results of supplemental (i.e. additional, more specific) tests as required in § 610.40(c) of this chapter;

(4) Information concerning appropriate medical followup and counseling; and

(5) Where applicable, the possibility that the donor may be found suitable for future donations.

(c) The notification process shall include a minimum of three attempts to

notify the donor and be completed within 8 weeks after the determination that the donor should be deferred or at the first return visit of the deferred donor after the determination is made, whichever is earlier.

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–21295 Filed 8–18–99; 8:45 am]

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