infection due to communicable disease agents listed in § 610.40(a); and

(2) Human immunodeficiency virus (HIV) test kit approved for use in the diagnosis, prognosis, or monitoring of this communicable disease agent.

(b) You must not distribute a lot that is found to be not acceptable for sensitivity and specificity under § 610.44(a). FDA may approve an exception or alternative to this requirement. Applicants must submit such requests in writing. However, in limited circumstances, such requests may be made orally and permission may be given orally by FDA. Oral requests and approvals must be promptly followed by written requests and written approvals.

§ 610.45 [Removed]

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

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

13. 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]

14. Section 640.2 *General requirements* is amended by removing paragraph (d).

15. Section 640.5 is amended by revising paragraph (f).

§ 640.5 Testing the blood.

* * * * *

(f) *Test for communicable disease agents.* Whole Blood shall be tested for evidence of infection due to communicable disease agents as required under § 610.40 of this chapter.

§ 640.14 [Amended]

16. Section 640.14 *Testing the blood* is amended by removing ''§§ 610.40 and 610.45'' and by adding in its place '' § 610.40''.

§ 640.23 [Amended]

17. Section 640.23 *Testing the blood* is amended in paragraph (a) by removing ''§§ 610.40 and 610.45'' and by adding in its place ''§ 610.40''.

§ 640.33 [Amended]

18. Section 640.33 *Testing the blood* is amended in paragraph (a) by removing ''§§ 610.40 and 610.45'' and by adding in its place ''§ 610.40''.

§ 640.53 [Amended]

19. Section 640.53 *Testing the blood* is amended in paragraph (a) by removing ''§§ 610.40 and 610.45'' and by adding in its place ''§ 610.40''.

20. Section 640.67 is revised to read as follows:

§ 640.67 Laboratory tests.

Each unit of Source Plasma shall be tested for evidence of infection due to communicable disease agents as required under § 610.40 of this chapter.

21. Section 640.70 is amended by revising paragraph (a)(2).

§ 640.70 Labeling.

(a) * * *

(2) The statement ''Caution: For Manufacturing Use Only'' for products intended for further manufacturing into injectable products, or the statement, ''Caution: For Use In Manufacturing Noninjectable Products Only'', for products intended for further manufacturing into noninjectable products. The statement shall follow the proper name in the same size and type of print as the proper name. If the Source Plasma has a reactive screening test for evidence of infection due to a communicable disease agent(s) under § 610.40 of this chapter, or is collected from a donor with a previous record of a reactive screening test for evidence of infection due to a communicable disease agent(s) under § 610.40 of this chapter, the Source Plasma must be labeled under § 610.40(h)(2)(ii)(E) of this chapter.

* * * * *

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 660.42 [Removed]

23. Section 660.42 *Reference panel* is removed.

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

24. The authority citation for 21 CFR part 809 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

25. Section 809.20 is amended by revising paragraph (b).

§ 809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

* * * * *

(b) *Compliance with good manufacturing practices.* In vitro diagnostic products shall be manufactured in accordance with the good manufacturing practices requirements found in part 820 of this chapter and, if applicable, with § 610.44 of this chapter.

Dated: June 1, 2001.

Bernard A. Schwetz,

Acting Principal Deputy Commissioner.

[FR Doc. 01–14408 Filed 6–8–01; 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; Donor Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to require blood and plasma establishments to notify donors, including autologous donors, whenever the donor is deferred or determined not to be suitable for current or future donations of blood and blood components. A donor is deferred based on results of tests for communicable disease agents or determined not to be suitable for donation based on failure to satisfy suitability criteria. Blood and plasma establishments also are required to notify the referring physician of an autologous donor when the autologous donor is deferred based on tests for evidence of infection with a communicable disease agent(s). A standard operating procedure (SOP) and recordkeeping also are required. This final rule is intended to help protect public health and to promote consistency in the industry. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule on the requirements for testing human blood donors for evidence of infection due to communicable disease agents.

DATES: This rule is effective December 10, 2001.

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. Background

In the **Federal Register** of August 19, 1999 (64 FR 45355), we (FDA) proposed to require that blood and plasma establishments notify donors of their deferral due to results of tests for communicable disease agents or based on failure to satisfy donor suitability criteria. We issued the proposed rule with the intent of reducing the risk of transmission of communicable disease from the use of blood, blood components, and blood derivatives. Under the proposed rule, blood and plasma establishments would: (1) Notify the donors that they are deferred based on results of tests for evidence of infection due to a communicable disease agent or based on suitability criteria, and the reason for the deferral; (2) where applicable, provide the results of tests for evidence of infection due to a communicable disease agent(s) that was the basis for deferral, including the results of supplemental (additional, more specific) tests; (3) provide information concerning appropriate medical followup and counseling; (4) describe the types of donations the donors should not donate in the future; and (5) discuss the possibility that the donor may be found suitable in the future, where appropriate. We proposed that the notification process should include a minimum of three attempts to notify the donor and be completed within 8 weeks after the donor was determined to be deferred or at the first return visit of the donor, whichever is earlier. FDA provided 90 days for comments on the proposed rule.

In the same issue of the **Federal Register** of August 19, 1999 (64 FR 45340), we proposed to revise the general biological product standards by updating the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing requirements by adding testing requirements for hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), and by adding requirements for supplemental (i.e., additional, more specific) testing when a donation is found to be reactive for any of the required screening tests for evidence of infection due to communicable disease agents. (No change was proposed to the requirements for serological tests for syphilis). We also proposed regulations for the deferral of donors based on the results of the screening test. FDA provided 90 days for comment.

In the **Federal Register** of November 9, 1999 (64 FR 61045), we announced a public workshop to be held on November 22, 1999, and also extended to December 22, 1999, the comment period on both proposed rules, i.e., ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents,'' and ''General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors.'' The purpose of the public meeting was to provide a public forum for gathering information and views regarding the proposed rules.

II. Highlights and Summary of the Final Rule

A. Plain Language

We have written the final rule using plain language consistent with the Presidential memorandum on plain language in Government writing, dated June 1, 1998. We have adopted the plain language approach making the rule more accessible and understandable to the public. As a result, we have used pronouns in describing who must comply, e.g., ''you'' is used to refer to an establishment that collects blood or blood components. We also have used ''must'' instead of ''shall.''

B. Final Rule

With this final rule, we created a new part 630 entitled ''General Requirements for Blood, Blood Components, and Blood Derivatives'' containing requirements for notification of deferred and unsuitable donors. Under § 630.6, establishments that collect blood or blood components must make reasonable attempts to notify all donors, including autologous donors, that they are deferred from further donations based on results of tests for evidence of infection due to communicable disease agents under part 610 or part 640 (21 CFR part 610 or part 640) in new § 610.41 or determined not to be suitable for donation based on failure to satisfy suitability criteria under § 640.3 or § 640.63. The establishment must provide the following information to the donor: (1) That the donor is deferred or determined not to be suitable for donation and the reason for that decision; (2) where appropriate, the types of donations of blood and blood components that 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, including results of supplemental (i.e., additional, more specific) tests; and (4) where appropriate, information concerning medical followup and counseling. The establishment must make reasonable attempts to notify the donor within 8 weeks of determining that the donor is deferred or determined not to be suitable for donation. The establishment must document that the donor has been successfully notified, or if unsuccessful, that the establishment made reasonable attempts to notify the donor. In addition to notifying an autologous donor, the establishment must notify the autologous donor's referring physician agents, with the same information and within the same time period, when the donor is deferred based on results of tests for evidence of infection due to communicable disease. Each establishment must prepare a SOP for donor notification and autologous donor referring physician notification, including the appropriate followup if the initial attempt at notification fails. Recordkeeping also is required.

This final rule on notification of donors is a companion rule to the final rule entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (testing final rule) found elsewhere in this issue of the **Federal Register**. The testing final rule revises the general biological product standards by updating the HBV and HIV testing requirements, by adding testing requirements for HCV and HTLV, and by adding requirements for supplemental (additional, more specific) testing when a donation is found to be reactive for any of the required screening tests for evidence of infection due to communicable disease agents. The testing final rule also requires the deferral of donors based on the results of screening tests for communicable disease agents, including syphilis. The requirements in the testing final rule are referenced throughout this document. Therefore, in order to understand fully the requirements of both rulemakings, they should be read together.

III. Comments on the Proposed Rule and FDA Responses

We received 14 letters of comment on the proposed rule, submitted by blood centers, hospitals, transfusion services, consumer advocacy groups, and professional associations. The comments predominantly supported the concept of promptly notifying donors that they are deferred based on results of tests for communicable disease agents or that they are determined not to be suitable for donation based on failure to satisfy suitability criteria. Some comments objected to FDA mandating how and when notification occurs. Others objected to specific requirements in the proposed rule. A summary of the comments and the agency's responses follow.

A . Scope of the Notification Rule

Proposed § 630.6(a) required an establishment that collects blood or blood components to notify donors who have been deferred based on results of tests for evidence of infection due to communicable disease agents or determined not to be suitable for donation based on failure to satisfy suitability criteria. In proposed § 630.6(b), the rule required the establishment to inform a donor that the donor is deferred or determined not to be suitable for donation and the reason for that decision. The establishment would also provide the following information: The types of donations of blood or blood components that the donor should not donate in the future; where applicable, the results of tests including supplemental (i.e., additional, more specific) tests; information concerning appropriate medical followup and counseling; and, where applicable, the possibility that the donor may be found suitable for future donations.

(Comment 1) Two comments suggested requiring notification of donors based on other criteria in addition to those deferred for results of tests for evidence of infection due to communicable disease agents and determined not to be suitable as a donor based on suitability criteria. One of the two comments suggested we require notification of donors deferred voluntarily by blood banks. The other comment argued that notification should apply to any preliminary test results carried out prior to blood or blood component collection.

Under the final rule, we are requiring notification of donors deferred based on results of required tests for evidence of infection due to communicable disease agents, or determined not to be suitable for donation due to failure to satisfy suitability requirements in §§ 640.3 and 640.63. The notification requirement is imposed in conjunction with requirements for testing for infection due to markers of certain communicable disease agents listed in new § 610.40 or for syphilis in §§ 640.5(a), 640.14, 640.23(a), 640.33(a), 640.53(a) and 640.65(b)(2), and for deferral of donors who test reactive for those markers in new § 610.41. The notification must include screening test results and the results of any approved supplemental (i.e., additional, more specific) tests. As we stated in the proposed rule, we are not requiring blood and plasma establishments to notify donors that are deferred voluntarily by blood and plasma establishments for a variety of medical reasons beyond what is required in the regulation. We believe notification of donors voluntarily deferred by a blood and plasma establishment should be left to the medical judgment of the blood or plasma establishment's medical director.

(Comment 2) Six comments argued that the proposed rule is too detailed on the method and content of notification. These comments argued that blood and plasma establishments need flexibility in how and what they tell donors about their deferred status. Further, the sensitivity of the information, the setting, and the donor's attitude may not lend themselves to the detailed notification included in the proposed rule. Several of the comments pointed out that most blood and plasma establishments follow the American Association of Blood Banks (AABB) standards and voluntarily notify donors, so FDA does not need to codify the details of notification.

The final rule provides blood and plasma establishments with the framework for notification of deferred donors and donors determined not to be suitable for donation. Donors who are deferred based on test results or determined not to be suitable for donation based on failure to satisfy donor suitability criteria must be informed that they are deferred or determined not to be suitable for donation and the reason for that decision. The donor must be given, where appropriate, a description of the types of donations the donor should not make in the future and information concerning medical followup and counseling. Where applicable, the donor must be provided the results of screening and supplemental tests for evidence of infection due to a communicable disease agent(s). In the final rule, our intent is not to remove from blood and plasma establishments the medical judgment necessary to inform donors fully of their potential infectious disease status. Rather, the final rule sets out the information the agency considers necessary to be provided to the donor. We recognize that some donors may need to be informed of the need for medical followup or counseling, others may not. A variety of factors may influence a blood and plasma establishment's decision to inform the donor in person, by phone, or by mail. The final rule is intended to help ensure consistency in the blood industry's notification practices. We believe uniform notification practices by blood and plasma establishments will improve blood safety by preventing donations by individuals at risk for transmitting communicable diseases.

(Comment 3) Five comments argued that the requirements of the proposed rule fall outside FDA's jurisdiction. These comments argued that donor notification and education don't affect the safety, purity, or potency of the blood supply because the donor is already deferred from future donations. The comments also argued that the manner of notification constitutes the practice of medicine best left to the discretion of the medical staff (or in the case of an autologous donor, the donor's referring physician) at the blood and plasma establishment, and should not be imposed on the collection site staff.

As we explained in the preamble of the proposed rule, notification of a donor is directly related to preventing the introduction and spread of communicable diseases. Through notification, a donor learns of the deferral and the need to refrain from future donations, as well as the medical significance of the deferral. Where appropriate, the donor is made aware of the need for further medical treatment or counseling. We do not agree that donor notification constitutes the practice of medicine. We believe that this information is pertinent to the donor's health status and that the donor must be made aware of such information in order to seek medical care as appropriate. Notification of donors is currently part of the AABB standards, which recommend that establishments notify donors of ''any medically significant abnormality detected during the predonation evaluation or as a result of laboratory testing'' (see section B3.500 of ''AABB Standards for Blood Banks and Transfusion Services,'' 19th edition, 1999). As many of the comments pointed out, this activity is currently performed as usual and customary business practice. The final rule also requires the establishment to develop SOP's for notifying donors and the referring physicians of autologous donors. A blood or plasma establishment that fails to comply with donor notification procedures is in violation of current good manufacturing practice (CGMP) and, therefore, is subject to the enforcement provisions of the Federal Food, Drug, and Cosmetic Act (the act).

(Comment 4) Two comments pointed out that several States have laws governing notification of donors and FDA's proposed requirements may conflict with State provisions and cause confusion for blood collection establishments.

We are aware of varying State requirements concerning notification of the State health authorities of a donor's positive test results, not of a donor's deferral. Such State laws require that the collecting establishment notify the State of certain communicable disease test results. The State may then notify the donor, but not always. Our requirements prescribe that the donor be notified directly of all test results that were the basis for deferral and be given information concerning medical followup and counseling. Our requirements are in addition to, and do not conflict with, State requirements.

(Comment 5) One comment supported providing donors with information about the possibility of requalification for donating and suggested expanding the requirement to include information regarding future donations even where there is no requalification process or method (algorithm) approved by FDA for such purpose. Two comments argued against notifying the donor of possible requalification. These comments argued that such information would make the notification too long and confusing and that blood and plasma establishments would be required to change their notification procedures every time requalification protocols change.

We have removed the requirement that blood and plasma establishments notify donors of the possibility that the donor may be found suitable for future donations. We removed this requirement because requalification of donors is not required and to explain the possibility of requalification to a donor would be an unnecessary burden for an establishment that does not have a requalification program. Under the related donor testing and deferral rule, blood and plasma establishments may use blood or blood components from a donor who was previously deferred as a result of testing reactive on a screening test(s) for specified communicable disease agent(s) if the blood or blood components currently test negative for those same disease agent(s) and the donor has been shown to be suitable to donate blood by an algorithm approved for that purpose by FDA. Blood and plasma establishments that requalify donors should consult FDA guidance on what to tell a donor about the possibility for future donation. Guidance documents may be obtained from the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance documents may also be obtained by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by FAX by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Persons with access to the Internet may connect to CBER at ''http://www.fda.gov/cber/publications.htm.''

B. Notification of Deferred Autologous Donors

We proposed several exceptions to donor deferral in related rulemaking that would affect donor notification. Autologous donors testing reactive for communicable disease agents would not be deferred. Collecting establishments would not be required to notify autologous donors who test reactive for a communicable disease agent(s). Nevertheless, we recommended that collecting establishments notify autologous donors, when applicable, for the purpose of medical followup and counseling. We also requested comments on whether to require notification of autologous donors of reactive and supplemental test results even though such donors would not be deferred.

(Comment 6) Three comments supported permanently deferring autologous donors from future allogeneic donations and notifying the autologous donors of their deferral using the same criteria as for allogeneic donors. These comments argued that autologous donors and allogeneic donors present the same risks for future allogeneic donations. The comments also argued that notification of autologous donors will help reduce the spread of communicable disease, and help prevent potentially infectious autologous donors from attempting to become allogeneic donors in the future. One comment pointed out that notification of autologous donors of the results of infectious disease testing is widely practiced already and therefore would not be a burden on blood and plasma establishments.

Under new § 610.40 found elsewhere in this issue of the **Federal Register**, autologous donations must be tested for evidence of infection due to communicable disease agents only if the blood or plasma establishment ships autologous donations or maintains a program that allows autologous donations to be used for allogeneic transfusion. In such case, if an autologous donor tests reactive, he or she must be deferred from allogeneic donations under new § 610.41. In order to prevent donation in the future, deferral under new § 610.41 triggers the notification requirements of the final notification rule. Notification of autologous donors also must include the test results that are the basis for deferral, if applicable; types of donations they should not make in the future; and where applicable, information concerning medical followup and counseling. Recognizing that autologous donation is also a medically ordered procedure, blood and plasma establishments also must notify the deferred autologous donor's referring physician that the donor has been deferred based on test results and the reasons for that decision, including test results that are the basis for deferral and the types of donations the autologous donor should not donate in the future for allogeneic use.

An allogeneic donor completes a preliminary screening and physical assessment prior to donation. If the allogeneic donor is determined not to be suitable for donation during this process, it is usual and customary business practice that the donor be notified on site that they are determined not to be suitable for donation and given the reason for that decision. We anticipate that any additional required information will be provided at that time. However, usually when an autologous donor donates, it is by a physician's prescription and the autologous donor may not always meet, and is not required to meet, all the preliminary screening and physical assessment criteria. Even when the autologous donor is determined not to be suitable for allogeneic use, the donation is collected and labeled under § 606.121 and the autologous donor must be provided the information required in § 630.6(b), i.e., the reason for the determination; if applicable, types of donations they should not make in the future; and where applicable, information concerning medical followup and counseling.

(Comment 7) Six comments suggested that abnormal test results should be sent only to an autologous donor's referring physician, not the donor. The comments argued that an autologous donor is a patient under physician care undergoing a medical procedure ordered by that physician. Under these circumstances, the comments argued it would be appropriate to give the test results to the referring physician, similar to any other laboratory results, and let that physician determine the need to notify the donor for medical followup. These comments argued that notifying the autologous donor directly could interfere with the doctor-patient relationship and result in conflicting advice. Several comments state that notifying the donor's

physician of test results is current industry practice. Two of the comments argued that there was no safety issue to justify notification of the autologous donor because reactive units would not enter the blood supply and few autologous donors return to donate allogeneic units.

Under the final rule, we are requiring blood and plasma establishments to notify both the autologous donor and the autologous donor's referring physician of the donor's deferral whenever the donor is deferred as required under new § 610.41. We believe that the referring physician needs to be informed of the reasons for the autologous donor's deferral due to test results. Such notification should include the results of any screening or supplemental tests so that the physician can make informed medical judgments about the donor as a patient. We also believe that the donor has a need to be informed of his or her deferral or determination not to be suitable, and the reasons for the decision, as well as any appropriate medical counseling or treatment. We believe notifying the deferred autologous donor is necessary both for the health of the donor and to help prevent deferred or unsuitable autologous donors from attempting future allogeneic donations if indicated. Autologous donors may wish to discuss the underlying reasons for the determination with their physicians.

C. Notification Based on Results of Tests for HTLV, Types I and II, and Anti-HBc

In the proposed rule, blood and plasma 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 reactive on a second occasion for anti-HTLV, types I and II, or anti-hepatitis B core (anti-HBc). The agency requested comments on whether to notify donors who test reactive for anti-HTLV, types I and II, or anti-HBc on only one occasion or to wait to notify donors upon testing reactive on the second occasion. Upon the availability of an approved supplemental (additional, more specific) test, a reactive donor would be deferred after a single reactive donation. At such time, blood establishments would notify donors of the test results of both the approved screening and supplemental tests.

(Comment 8) Four comments were submitted on the notification of donors testing reactive for anti-HTLV, types I and II, or anti-HBc. Two comments favored notifying the donor when the donor is deferred, i.e., after the reactive screening test on a second occasion. Another comment suggested notifying the donor after the reactive screening test on the first occasion, but not to defer until the reactive screening test occurs on a second occasion. One comment stated that the reliability of the tests for anti-HTLV, types I and II or anti-HBc is low enough that donor notification should not be required.

After reviewing the comments and further evaluation, we have decided to require blood establishments to notify donors who test reactive for anti-HTLV, types I and II, or anti-HBc on two occasions and, consequently, are deferred. Because an approved supplemental test for HTLV, types I and II, or anti-HBc is not currently available to aid in the notification, we believe it is appropriate that blood and plasma establishments not be required to notify donors after a reactive screening test on the first occasion due to the high rate of false reactivity in low risk blood bank settings. However, under new§ 610.40(h)(1), the donation that tests reactive must not be shipped or used, and the donor remains in the donor pool until the donor tests reactive on a second occasion. It is our intent that if licensed supplemental tests for HTLV, types I and II, or anti-HBc are approved, blood establishments would be required to defer donors after a reactive donation on the first occasion regardless of the results of the supplemental (additional, more specific) tests and notify the donor of both the screening and supplemental test results as prescribed in § 630.6(b).

D. Notification of Donors Determined Not to Be Suitable for Donation Based on Failure to Satisfy Suitability Criteria

The proposed rule would require blood and plasma establishments to notify donors who are determined not to be suitable based on failure to satisfy donor suitability criteria.

(Comment 9) Five comments called for clarification of what suitability requirements would trigger notification of a donor determined not to be suitable for donation.

Currently, the regulations defining donor suitability in §§ 640.3 and 640.63 apply to all donations, including autologous donations. See comment 6 of this document for further discussion of notification of an autologous donor when determined not to be suitable for donation.

(Comment 10) Several comments argued that blood and plasma establishments already voluntarily notify donors based on failure to satisfy suitability criteria on site so the proposed rule is not necessary and too burdensome.

We believe that notification of donors based on failure to satisfy suitability requirements is necessary to help ensure consistency in industry practice and further improve the safety of the blood supply. We do not believe the final rule is too burdensome as it codifies what many blood and plasma establishments already are performing as usual and customary business practice. As the final rule discusses in section III.E of this document, notification of donors based on determination not to be suitable still may occur on site at the time of deferral.

(Comment 11) Two comments stated that criteria used in determining the donor not to be suitable for donation and notification of the donor are decided by medical professionals at blood and plasma establishments and constitute the practice of medicine. Consequently, the comments believed the proposed rule goes beyond FDA's jurisdiction.

We disagree with the comments. We believe that donor testing, deferral, and notification are within our jurisdiction because they relate to the safety of blood products and the control of communicable disease. We believe the deferral and notification requirements will help ensure that the Nation's blood supply is safe by excluding donors who may present significant risks from donation in the future. These requirements also will enhance the public health by helping to ensure that those donors who have been deferred or determined not to be suitable for donation are advised to seek treatment and counseling, where appropriate.

(Comment 12) One comment argued that requiring blood and plasma establishments to notify donors based on their failure to satisfy suitability criteria under the proposed rule may create a patient-physician relationship between the donor and the blood and plasma establishment, therefore violating statutes that prohibit the corporate practice of medicine.

We disagree with the comment. Our intention is not to encourage the practice of medicine by the blood and plasma establishments, but to help ensure that blood and plasma establishments help prevent the potential spread of communicable disease and provide valuable information that may affect the donor's health so that the donor can seek medical care as appropriate. We have revised the language in § 630.6(b) of the final rule to support these intentions.

(Comment 13) Two comments argued that notification of a donor based on

failure to meet suitability criteria is done on site at the time of donation, so blood and plasma establishments should not be required to make three attempts at notification at some later date.

The final rule is not prescribing the method of notification to be used. This will allow the blood and plasma establishments to determine the best method of notification for a particular donor. This flexibility allows a collecting establishment to notify the donor on site either at the time of the donor's screening and physical assessment or at the time of the donor's return visit, by phone, or by mail.

The final rule requires that the blood or plasma establishment make reasonable attempts to notify donors. For example, an establishment may send a notification letter by regular mail to a donor in compliance with § 630.6. A week later, the letter is returned to the establishment by the post office marked ''address unknown.'' The establishment could then proceed with the additional steps until successful notification occurs, or until it is clear that further attempts will not be successful. Such steps could include: Checking the record of the donor's address for transcription error; or searching a local phone book for a correct address and then, in either case, resending the letter. Additionally, the establishment could phone the donor and either notify the donor at that time or ask for a correct address in order to resend the letter.

The final rule also clarifies that a blood or plasma establishment must make reasonable attempts to notify the donor within 8 weeks after determining the donor is deferred or not suitable until the establishment actually succeeds in notification or until the blood and plasma establishment makes sufficient reasonable attempts at notification and it is clear that further attempts will not be successful. A blood and plasma establishment that successfully notifies on site at the time of donation would not have to notify further a donor determined not to be suitable for donation based on failure to satisfy suitability criteria under §§ 630.6 and 640.63.

(Comment 14) One comment argued that blood and plasma establishments should be allowed to notify donors determined not to be suitable for donation based on failure to satisfy suitability criteria by providing the donors with generic letters on site.

The final rule does not prohibit this method of notification as longas a blood or plasma establishment can fully meet the requirements of §§ 630.6 and 630.63 by including the necessary information in a standardized letter. However, blood and plasma establishments may need to supplement such a letter on a case-by-case basis with information specific to the donor.

(Comment 15) Two comments pointed out that many donors determined not to be suitable for donation based on failure to satisfy suitability criteria do not need further treatment or counseling.

We agree with the comment. In the final rule, we clarify the intent to require blood and plasma establishments to provide donors, deferred or determined not to be suitable for donation, with information concerning medical followup, treatment or counseling only when applicable to a particular donor. We recognize that for some donors referral to medical followup or counseling would be unnecessary.

(Comment 16) One comment argued that the proposed rule should not treat donors deferred based on test results in the same manner as donors determined not to be suitable for donation based on failure to satisfy suitability criteria because the former have known health problems while the latter probably do not.

We disagree with the comment. Both reactive test results for communicable disease agents and failure to satisfy suitability criteria raise health concerns for the donor of which the donor should be aware. However, the information provided in the notification may vary, depending on the reason for the deferral or determination not to be suitable for donation based on failure to satisfy suitability criteria.

E. Method of Notification—How to Notify the Donor

The preamble of the proposed rule discussed the possibility that blood and plasma establishments would be able to fulfill the notification requirements on site. It explained that some blood and plasma establishments may notify donors by registered mail, return receipt; or may choose to request that the donor return for direct donor notification. In the preamble of the proposed rule, FDA requested comments on the methods of notification that would help ensure adequate donor confidentiality and the current application and sufficiency of Federal, State, and local laws that protect the privacy of the individual being notified.

(Comment 17) Four comments argued that blood and plasma establishments should have flexibility in the manner they meet their notification obligations under § 630.6(b) and in the way they protect donor confidentiality. No comments were received on the current application and sufficiency of the Federal, State, and local laws that protect the privacy of the individual being notified.

Under the final rule, blood and plasma establishments have the flexibility to choose the manner in which they notify donors. Provided that their notification obligations are fulfilled within 8 weeks, blood and plasma establishments may choose to notify a donor: (1) In person at the time of actual deferral, (2) in person at the donor's first return visit, (3) by phone, or (4) by mail.

Personnel performing this activity must be adequately trained as required under § 606.20. One method of notification that helps ensure donor confidentiality is person-to-person contact.

(Comment 18) Seven comments objected to FDA requiring that notification be sent by registered mail. These comments argued that some donors will not open registered mail and others will be unnecessarily alarmed by receipt of such a letter. The comments stated that sending notification by certified mail will not guarantee that the donor receives it and will add significant expense unnecessarily. The comments suggested that a letter sent by regular mail, documented by the blood or plasma establishment, should be sufficient.

The preamble of the proposed rule only discussed the possibility of notification by certified mail. Blood and plasma establishments may fulfill their notification obligations by regular mail provided they do so within 8 weeks after determining that the donor is deferred or is not suitable to donate and they document their notification attempts.

(Comment 19) Two comments asked for FDA to allow notification of a donor by telephone or by letter providing a telephone number that the donor can call for information regarding the deferral.

The final rule does not preclude notification by telephone provided a blood or plasma establishment meets all of its notification obligations under § 630.6 and documents notification of the donor.

(Comment 20) Five comments objected to FDA requiring blood and plasma establishments to make three attempts to notify donors deferred based on results of tests for communicable disease agents or determined not to be suitable for donation based on failure to satisfy suitability criteria. These comments argued that the first attempt should be sufficient because it is made

shortly after the donation and subsequent attempts are unlikely to succeed.

We clarify in the final rule that a blood or plasma establishment must make reasonable attempts to notify the donor. We eliminate the requirement for three attempts to emphasize that a blood or plasma establishment should continue attempting to notify a donor until it is clear that further attempts would not be successful. If the initial attempt or attempts are unsuccessful, a blood or plasma establishment may need to try other methods to contact the donor. If a blood or plasma establishment is successful in notifying a donor then, obviously, no other attempts are necessary. Blood and plasma establishments must document their attempts to notify donors and maintain a record of these attempts, whether successful or not.

(Comment 21) One comment suggested 8 weeks is not enough time for blood and plasma establishments to complete notification because some confirmatory test results take longer to be completed. Another comment argued that 8 weeks is too long a timeframe for notification.

We believe blood and plasma establishments will be able to complete notification or reasonable attempts to notify the donor within the prescribed 8-week timeframe. Blood and plasma establishments must attempt to obtain the results of supplemental tests prior to notifying donors of their deferral. However, if the results were unavailable prior to notification, blood and plasma establishments would be required to renotify the donor with the results of the supplemental testing. We believe that the results of tests for communicable disease agents, including approved supplemental tests, should generally be available within the 8-week notification timeframe.

F. Permanent Address

In proposed § 606.160(b)(1)(x), FDA proposed to require the blood or plasma establishment to record the donor's permanent address to facilitate the notification of the donor.

(Comment 22) Five comments objected to FDA requiring proof of a permanent fixed address. These comments question what proof of a permanent, fixed address would be acceptable and point out that certain donors may not be able to provide such proof. The comments argued it is not logical that voluntary donors would misrepresent their address. Several of these comments point out that donors may have privacy concerns for not giving a permanent address.

We clarify in the final rule that blood and plasma establishments need to obtain and keep a record of an address where the donor represents he or she can be reached within 8 weeks after donation. A donor does not need to prove that the provided current address is fixed or permanent.

IV. Analysis of Impacts

FDA has examined the impacts of the 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 in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The Office of Management and Budget (OMB) has determined that this rule 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 an expenditure in any one year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates 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 rule is not expected to have a significant economic impact on a substantial number of small business entities because donor notification is considered usual and customary business practice for the affected entities.

A. Objectives and Basis of the Action

As discussed previously, FDA is implementing this action to helpprotect the public health and promote consistency in the industry. 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 who fail to satisfy suitability criteria are excluded from donating blood and blood components. Once donors are deferred from donation or determined not to be suitable for donation, they would be informed of the deferral or determination and the reason for that decision; the types of donations they should not donate in the future; the screening and supplemental test results, if applicable; and information concerning 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 to minimize the risk of transmitting the disease agent.

This action is taken under the authority of sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 264 *et seq.*) and the provisions of the act that apply to drugs, specifically section 501 of the act (21 U.S.C. 351), in order 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, the blood or plasma establishment 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 rule.

B. Nature of the Impact

The rule requires that blood and plasma establishments notify donors, including autologous donors, of their deferral because of the results of testing for evidence of infection due to communicable disease agents including HIV, HTLV, hepatitis B, hepatitis C, or syphilis or that they are determined not to be suitable for donation based on failure to satisfy suitability criteria. Blood establishments also are required to notify referring physicians of autologous donors of reactive test results for evidence of infection due to communicable disease agents. Under the rule, the donor must be notified of the types of blood or blood components that the donor should not donate in the

future, where appropriate. The notification must include the results of tests for evidence of infection due to communicable disease agents including the results of supplemental tests, if applicable, and where appropriate, the types of donation of blood or blood components that the donor should not donate in the future, and information concerning medical followup and counseling. The establishments must make reasonable attempts to notify the donor within 8 weeks of the donor deferral or determination not to be suitable for donation. In order to implement this notification process, the rule also requires that blood and plasma establishments obtain and record an address for each prospective donor. Establishments must also maintain records of attempts to notify a deferred or unsuitable donor within the prescribed timeframe. An establishment also must prepare SOP's describing all steps required in the notification process.

C. Type and Number of Entities Affected

The donor notification requirements will affect all blood and plasma establishments that collect blood and blood components. FDA's registration data base for blood and plasma establishments has record of approximately 1,041 establishments: 60 licensed plasma establishments with multiple locations and 981 registered blood establishments. The AABB estimates that approximately 12.6 million blood donations are collected annually. Allogeneic blood donations have recently accounted for an estimated 87.2 percent of that total with autologous donations comprising an additional 8.1 percent and directed donations averaging 3.2 percent (Ref. 1). In 1997, the General Accounting Office (GAO) estimated that approximately 12 million donations of Source Plasma were collected by plasma centers.

D. Estimated Impact of Requirements for Donor Notification

The rule is expected to have a minor net impact on blood and plasma establishments because it is already usual and customary business practice in the blood industry to notify donors that are deferred or determined not to be suitable for donation; virtually all establishments include this process within current operational guidelines. FDA expects that the primary impact of the rule will include a one-time review effort at each facility and a more extensive notification process at those facilities that currently perform donor notification over a longer timeframe or with fewer notification attempts. The agency received one letter of comment on the estimated one-time burden on the blood and plasma establishments in complying with the requirements of the rule.

(Comment 23) One comment asserted that the review of the regulation alone would require at least 4 hours of staff time to comprehensively understand the directives. Another comment in the letter asserted that revisions to procedures could not be accomplished in only 4 hours, noting that notification letters and computer software would have to be revised, staff would have to be trained, and there may be a need to purchase new equipment such as printers.

FDA agrees that the estimated time of 4 hours did not adequately account for time spent for revising the establishment's SOP's in addition to reviewing the regulations. Therefore, we are revising the estimated time for review of the regulation and revision of an establishment's SOP's to 8 hours for those establishments that currently maintain donor records and have notification procedures in place similar to those required by this rule. FDA agrees that establishments that make substantial changes to their notification processes (such as the information contained in their notification letters) will require more time. The agency assumes such facilities will require 24 hours of staff time and FDA uses this assumption in its cost models. FDA does not believe this donor notification rule requires a capital investment in new equipment.

The one-time effort to review and modify current SOP's is expected to vary among the 1,041 establishments, depending on the extensiveness of a facility's current protocols for 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 8 hours of staff time to reconcile the regulations against the facility's current standards. A technical specialist who acts as a regulatory reviewer or manager of quality assurance could perform this process. 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 $205 per establishment. For establishments that already perform donor notification but provide different information to donors or have established a different notification process than specified in the rule, FDA assumes that approximately 24 hours of staff time would be required to align current SOP's and recordkeeping with the provisions of the rule. The cost in this case would be approximately $616 per establishment. 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 1,041 currently operating establishments, and a more extensive review is conducted by the other one-third, the total one-time cost for the blood and plasma industries is estimated to be $356,022 ((2/3 x 1,041 x $205)) + (1/3 x 1,041 x $616)).

The yearly increase in cost is based on the ongoing notification of donors. FDA assumes that all donors determined not to be suitable for donation based on the screening interview can be notified onsite at the time of the determination, and provided with the appropriate 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 the following numbers: (1) 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 (a prevalence rate of 121.9 per 100,000 for viral markers among prospective donors) (Ref. 2); (2) that approximately 80 percent of donations are made by repeat donors[1] (12.6 million x .80 = 10.08 million blood donations and 12 million x .80 = 9.6 million plasma donations); (3) that repeat donors average two donated units per year[2] (10.08 million/2 = 5.04 million blood donors and 9.6 million/2 = 4.8 million plasma donors); and (4) that the first time donors contribute one unit per year (12.6 million—10.08 million = 2.52 million blood donors and 12 million—9.6 million = 2.4 million plasma donors). As a result, an estimated 9,264 deferred blood donors and 8,777 deferred plasma donors (including first time and repeat donors) would be notified each year, or a total of 18,041 annual notifications.

FDA assumes that all facilities currently make at least one notification attempt for all donors deferred based on

[1] This percentage is based on American National 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 Centers for Disease Control's analysis of blood donations prepared for HCV lookback.

test results. However, the percentage of facilities that would attempt notification more than once within an 8-week period is not known. FDA has therefore estimated the economic impact for a scenario in which the cost of compliance is based on the assumption that in one-fourth of the 18,041 notifications or 4,510, two additional notification attempts are needed, a phone call and a letter once the address has been corrected for a transcription error. This estimate is conservative and likely overstates the true frequency. The cost for these two notifications are estimated to be the cost of 0.5 hours of staff time for the phone call or $12.84, and 0.25 hours per staff time and 33 cents for the mailing or $6.75, for a total cost of approximately $19.59. The cost of compliance would be $181,482 [9,264 x $19.59] for the blood industry, and an estimated $171,941 [8,777 x $19.59] for the plasma industry. Because autologous donations constitute approximately 8 percent of all donations and these donations are referred by physicians, the rule requires establishments to send notifications to both the autologous donor and the referring physician. FDA estimates that the blood industry would incur an additional cost of $14,519 [$181,482 x .08], for a total of $196,001.

E. Expected Benefits of the Rule

As described in the preamble to this rule, notification of donors thatthey have been deferred or determined not to be suitable and consequently should not attempt subsequent donations will help prevent unsafe units of blood or blood components from entering the blood supply. Notified donors can then self-defer in the future and help protect the Nation's blood supply. In & FDA's proposed rule on donor testing (64 FR 45340, August 19, 1999), 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 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 a regulatory flexibility analysis. The blood and plasma establishments affected by the rule are included under the major standard industrial classification (SIC) code major group 80 for providers of health services.[3] 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 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 the field. A ''small government jurisdiction'' generally means government of cities, counties, town, townships, villages, school districts, or special districts, with a population of less than 50,000.[4]

As noted in the foregoing analysis, the rule is expected to have some cost impact on both plasma and blood collection centers. FDA has record of a total of 60 licensed plasma centers with multiple locations. FDA estimates that the vast majority of the plasma is processed by eight companies and that these companies own 90 percent of the plasma centers. FDA assumes that the other 52 plasma centers not associated with the eight companies may qualify as small business establishments. FDA has estimated that only 10 percent of plasma locations are owned by the 52 small entities. The potential impact on plasma collection facilities will be a function of the number of donors and the viral marker rates at their facility. The net impact on these facilities, however, is expected to be minor. If the estimated additional yearly cost of $171,941 was spread evenly over all locations, then the yearly cost to all 52 small entities would be $17,194 [$171,941 x 0.10], or approximately $331 [$17,941 / 52] per small entity 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 organization 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 donor notification at these facilities, and the relatively small number of donors that FDA estimates will be notified based on blood test findings, the impact on these small facilities is expected to be minor. Based on FDA's calculations, the 34 facilities with 30,000 donations or fewer per year, would identify an estimated 37 deferred donors per year through blood testing (30,000/100,000 x 121.9 = 37). If these facilities currently need to make two additional notification attempts under this rule, there would be an average small facility notification cost of $724 (37 x $19.59) per year. Because the estimated one-time cost for the review and revision of current deferral notification SOP's averages $342 (2/3 x $205 + 1/3 x $616) per establishment, the average annualized cost impact for the smaller collection establishments would be about $1,066 ($724 + $342), or roughly $0.04 per donation, assuming approximately 30,000 donations per year.

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

To minimize the impact on small entities while continuing to protect public health, the agency does not require donor notification until after the results of the approved supplemental testing are available.

As an alternative to this rule, FDA considered not requiring donornotification of deferral from future donation due to communicable disease testing or failure to satisfy suitability criteria 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 issued recommendations to establishments on notifying donors of deferral, the establishments have provided the deferred donor with inconsistent information and counseling. 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 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.

[3] A description of SIC major group 80 can be found at: http://www.osha.gov/cgi-bin/sic/sicser4?80.

[4] The SBA criteria for small business, listed by SIC code can be found at: http://www.sba.gov/regulations/siccodes/siccodes.pdf.

In the proposed version of this rule, the agency considered making the notification of reactive autologous donors recommended, but not mandatory, and that these donors not be deferred. In the final rule, the agency is requiring that reactive autologous donors, and their referring physicians, be notified and that these donors be deferred. The agency believes that that notification of autologous donors and their referring physicians will generate many of the same benefits as notification of allogeneic donors.

V. The Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the 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 below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification.

Description: This final rule amends §§ 606.100(b)(20) (Standard Operating Procedures), and 606.160(b)(1)(ix to xi) (Records), and adds new part 630 (Donor Notification), all of which contain new information collection.

A. Standard Operating Procedures (§ 606.100(b)(20))

Section 606.100(b)(20), requires blood and plasma establishments to write, maintain, and follow SOP's for donor deferral, donor notification, including autologous donors, and notification of referring physicians of autologous donors. This provision also requires SOP's for appropriate followup if the initial attempt at notification fails.

B. Records (§ 606.160(b)(1)(ix) to (b)(1)(xi))

Under § 606.160(b)(1)(ix) and (b)(1)(xi) establishments must maintain records of each notification and notification attempts of allogeneic donors, autologous donors, and the referring physicians of autologous donors. Section 606.160(b)(1)(x) requires establishments to record where the donor may be contacted within 8 weeks of donation.

C. Donor Notification (New Part 630)

Section 630.6(a) requires establishments collecting blood or blood components to make reasonable attempts to notify donors, including autologous donors, who are deferred based on the results of tests for evidence of infection due to a communicable disease agent(s) including syphilis; or determined not to be suitable for donation based on failure to satisfy suitability criteria. Section 630.6(b) requires that notification contain the following information: (1) The donor is deferred or determined not to be suitable for donation, and the reason for that decision; (2) the types of blood or blood components the donor should not donate in the future, where appropriate; (3) the establishment must provide the results of the test for evidence of infection due to the communicable disease agent(s) including syphilis that was the basis for the deferral and results of supplemental (additional, more specific) tests, when applicable; and (4) where appropriate, the establishment must provide information concerning medical followup and counseling.

Under § 630.6(d)(1), the establishment must notify the referring physician of an autologous donor when the autologous donor is deferred under new § 610.41. This notification must provide the same information as required for the notification of a donor.

Description of Respondents: Blood and plasma establishments that collect blood, and blood components, including Source Plasma.

As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on the information collection requirements of the proposed rule (64 FR 45355). In accordance with the PRA, OMB reserved approval of the information collection burden in the proposed rule stating that they will make an assessment in light of public comments received on the proposed rule. Two letters of comment on the information collection burden were submitted to the docket.

(Comment 24) One comment, in response to our notification estimate of a half hour, stated that notification and providing the required information would more likely take at least 1 hour, especially for individuals apparently infected with HIV, HBV, or HCV. The comment also stated that providing followup testing (supplemental) is more likely to take at least half an hour.

FDA agrees with the comment and is revising the estimated hours per response in table 1 of this document to 1.5 hours for notifying a donor with reactive screeningtest results.

(Comment 25) One comment suggested that the burden of the recordkeeping requirements for documenting the attempts to contact the donor is significantly underestimated.

The comment did not provide information supporting the statement that the burden is underestimated. Therefore, we continue to estimate the time for recording the notification of each donor as an average of 3 minutes.

(Comment 26) One comment opined that the estimate of 1.2 percent for donors who are deferred from donating due to failure to satisfy suitability criteria is far below actuality and that the number of donors deferred as a result of health history questions average 13 percent.

We have revised our estimate to reflect that an average of 13 percent of donors annually are determined not to be suitable for donation based on failure to satisfy suitability criteria.

According to FDA's registration data base, there are currently about 1,041 establishments affected by this rule: Approximately 60 licensed plasma establishments with multiple locations that collect Source Plasma, and approximately 981 registered blood and plasma establishments that collect blood and blood components. The number differs from the number of respondents estimated in the proposed rule (2,800) because we incorrectly included in the estimated number all registered establishments, including those that do no collect blood and plasma. Based on estimates provided by AABB and GAO, these establishments collect annually approximately 12.6 million donations of blood and blood components from approximately 8 million donors and approximately 12 million donations of Source Plasma from 1.5 million donors. As part of the 12.6 million donations of blood and blood components, AABB also estimates that approximately 643,000 autologous donations are collected annually. Assuming each autologous donor makes an average of 2 donations, we estimate that there are approximately 321,500 autologous donors.

D. Annual Reporting Burden (Table 1)

Industry estimates that approximately 13 percent of 9.5 million donors (1.2 million donors) who come to donate annually are determined not to be suitable for donation prior to collection because of failure to satisfy suitability criteria. It is the usual and customary business practice of virtually all 1,041 collecting establishments to notify on site and to explain the reason why the

donor is determined not to be suitable for donating. Based on such information as is available to FDA, we estimate that two-thirds of collecting establishments (697) provide on site additional information and counseling to a donor determined not to be suitable for donation as usual and customary business practice. Consequently, we estimate that only one-third or 344 collection establishments would need to provide additional information and counseling on site to 400,000 total donors. Industry representatives estimated that it takes on average approximately 5 minutes to provide appropriate health information to a donor determined not to be suitable for donation.

GAO estimates that another 4.5 percent of 9.5 million donors (427,500 donors) are deferred annually based on test results. We estimate that currently 95 percent of the establishments that collect 98 percent of the blood and blood components notify donors who have reactive test results for HIV, HBV, HCV, HTLV, and syphilis as usual and customary business practice. Consequently, 5 percent (52) of the industry collecting 2 percent (8,550) of the deferred donors would experience new burden related to this requirement. We have adjusted our original estimate of 15 minutes to complete the notification process to 1 hour based on comment from industry. Based on the same comment, we have also adjusted the time estimated for additional counseling of the donor once notification is received from 15 minutes to 30 minutes. The total for notification of each donor is 1.5 hours. As part of usual and customary business practice, collecting establishments notify an autologous donor's referring physician of reactive test results obtained during the donation process. However, we estimate that 5 percent of the 981 blood collection establishments (52) do not notify the referring physicians of the estimated 2 percent of 321,500 autologous donors with reactive test results (6,430). The time for these establishments to notify the referring physician is estimated at 1 hour.

E. Recordkeeping Burden (Table 2)

We estimate that 1,041 establishments will each expend, as a one-time burden, an average of 8 hours to reconcile their SOP's with the requirements (one-time burden of 7 hours to revise and an on-going burden of 1 hour to maintain). All plasma and blood establishments record each donor's address as part of their usual and customary business practice and, therefore, the requirement under § 606.160(b)(1)(x) does not create new or additional burden. Section 606.160(b)(1)(ix) requires that establishments record the notification efforts. We estimate that it will take 3 minutes on average to record the notification status of each of the 1.2 million donors determined not to be suitable to donate and each of the 427,500 donors deferred based on reactive test results for evidence of infection due to communicable disease agents. Section 606.160(b)(1)(xi) requires that records be kept regarding an establishment's efforts to notify the referring physician of a deferred autologous donor. Only the 981 registered blood establishments collect autologous donations and therefore are required to notify referring physicians. We estimate that 4.5 percent of the 321,500 autologous donors (14,468) will be deferred under new § 610.41, and thus result in the notification of their referring physicians.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. ofRespondents	AnnualFrequency perResponse	Total Annual Responses	Hours perResponse	Total Hours
630.6(a)[2]	344	1,163	400,000	0.08	32,000
630.6(a)[3]	52	164	8,550	1.5	12,825
630.6(d)(1)	52	124	6,430	1	6,430
Total					51,255

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notification of donors determined not to be suitable for donation based on failure to satisfy suitability criteria.
[3] Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

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) (maintenance of SOP's)	1,041	1	1,041	1	1,041
606.160(b)(1)(ix)	1,041	1,563	1,627,500	0.05	81,375
606.160(b)(1)(xi)	981	15	14,468	0.05	723
Total					83,139

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

TABLE 3.—ESTIMATED ONE-TIME RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b)(20)	1,041	1	1,041	7	7,287

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

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. 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. 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 to 812.

2. 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 entitled ''Demographic Characteristics, Unreported Risk Behaviors, and the Prevalence and Incidence of Viral Infections: A Comparison of Aphersis and Whole-Blood Donors,'' *Transfusion*, April 1998, vol. 38, pp. 350 to 358.

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, parts 606 and 630 are amended as follows:

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

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

Authority: 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 procedures for donor notification and autologous donor referring physician 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) to (b)(1)(xi) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(ix) Records of notification of donors deferred or determined not to be suitable for donation, including appropriate followup if the initial attempt at notification fails, performed under § 630.6 of this chapter.

(x) The donor's address provided at the time of donation where the donor may be contacted within 8 weeks after donation.

(xi) Records of notification of the referring physician of a deferred autologous donor, including appropriate followup if the initial notification attempt fails, performed under § 630.6 of this chapter.

* * * * *

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, 264.

§ 630.6 Donor notification.

(a) *Notification of donors.* You, an establishment that collects blood or blood components, must make reasonable attempts to notify any donor, including an autologous donor, who has been deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as required by § 610.41 of this chapter; or who has been determined not to be suitable as a donor based on suitability criteria under § 640.3 or § 640.63 of this chapter. You must attempt to obtain the results of supplemental testing required under § 610.40(e) of this chapter prior to notifying a donor of the deferral. If notification occurs prior to receipt of such results, you must also notify a deferred donor of the results of the supplemental testing. You must notify a donor as described in paragraph (b) of this section.

(b) *Content of notification.* You must provide the following information to a donor deferred or determined not to be suitable as a donor as described in paragraph (a) of this section:

(1) That the donor is deferred or determined not to be suitable for donation and the reason for that decision;

(2) Where appropriate, the types of donation of blood or blood components that 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(e) of this chapter; and,

(4) Where appropriate, information concerning medical followup and counseling.

(c) *Time period for notification.* You must make reasonable attempts to notify the donor within 8 weeks after determining that the donor is deferred or determined not to be suitable for donation as described in paragraph (a) of this section. You must document that you have successfully notified the donor or when you are unsuccessful that you have made reasonable attempts to notify the donor.

(d) *Autologous donors.* (1) You also must provide the following information to the referring physician of an autologous donor who is deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as described in paragraph (a) of this section:

(i) Information that the autologous donor is deferred based on the results of tests for evidence of infection due to communicable disease agent(s), as required under § 610.41 of this chapter, and the reason for that decision;

(ii) Where appropriate, the types of donation of blood or blood components

that the autologous donor should not donate in the future; and

(iii) 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(e) of this chapter.

(2) You must make reasonable attempts to notify the autologous donor's referring physician within 8 weeks after determining that the autologous donor is deferred as described in paragraph (a) of this section. You must document that you have successfully notified the autologous donor's referring physician or when you are unsuccessful that you have made reasonable attempts to notify the physician.

Dated: June 1, 2001.

Bernard A. Schwetz,

Acting Principal Deputy Commissioner.

[FR Doc. 01–14409 Filed 6–8–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 989

RIN 0701–AA56

Environmental Impact Analysis Process (EIAP); Correction

AGENCY: Department of the Air Force, DoD.

ACTION: Final rule; correction.

SUMMARY: The Department of the Air Force published in the **Federal Register** of March 28, 2001, a document concerning correcting amendments. This document corrects the inadvertent change to correcting amendment 45.

DATES: Effective on July 11, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Jack Bush (HQ USAF/ILEB), 1260 Air Force Pentagon, Washington, DC 20330–1260, (703) 604–0553.

SUPPLEMENTARY INFORMATION: In 32 CFR part 989, FR Doc. 01–7671 published on March 28, 2001 (66 FR 16868) make the following correction. On page 16869, correcting amendment 45, Appendix C, paragraph A3.1.3, last sentence, correct ''USAF/ILEVP'' to read ''HQ USAF/ILEVP.''

Dated: May 31, 2001.

Janet A. Long,

Air Force Federal Register Liaison Officer.

[FR Doc. 01–14681 Filed 6–8–01; 8:45 am]

BILLING CODE 5001–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[FRL–6995–2]

RIN 2060–AE56

Standards of Performance for Electric Utility Steam Generating Units for Which Construction is Commenced After September 18, 1978; Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of direct final rule.

SUMMARY: Due to relevant adverse comment, the EPA is withdrawing two provisions from the direct final rule published on April 10, 2001 for Subpart Da—Standards of Performance for Electric Utility Steam Generating Units for Which Construction is Commenced After September 18, 1978, and Subpart Db—Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units (66 FR 18546). These provisions deal with the revised definition of ''boiler operating day'' and the data substitution requirement for missing data.

DATES: This rule is effective June 11, 2001. As of June 11, 2001, the EPA withdraws the revised definition of ''boiler operating day'' in 40 CFR § 60.41a and 60.46a(j)(2) published on April 10, 2001 (66 FR 18546). The remaining provisions published on April 10, 2001 will be effective June 11, 2001 as stated in the April 10, 2001 direct final rule. The addition of 40 CFR 60.46a(j)(2), which deletes the data substitution requirement for missing data, is effective June 11, 2001.

ADDRESSES: Docket number A–92–71, containing supporting information used in the development of this notice is available for public inspection and copying between 8:00 a.m. and 5:30 p.m., Monday through Friday (except for Federal holidays) at the following address: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (6102), 401 M Street, SW, Washington, DC 20460, or by calling (202) 260–7548. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Mr. James Eddinger, Combustion Group, Emission Standards Division (MD–13), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, NC 27711, telephone number (919) 541–5426, electronic mail address: eddinger.jim@epa.gov.

SUPPLEMENTARY INFORMATION: Because EPA received relevant adverse comment, we are withdrawing two of the provisions included in the direct final rule for compliance and monitoring requirements for duct burners used in combined cycle systems. We published the direct final rule (66 FR 18546) and a notice of proposed rulemaking (66 FR 18579) intended to amend the emissions monitoring and compliance provisions for duct burners contained in subparts Da and Db on April 10, 2001.

We stated in that **Federal Register** that if we received relevant adverse comment by May 10, 2001 on one or more distinct provisions of the direct final rule, we would publish a timely withdrawal of those distinct provisions in the **Federal Register**. We subsequently received relevant adverse comment on two of the provisions: the revised definition of ''boiler operating day'' in 40 CFR 60.41a and the data substitution requirement contained in 40 CFR 60.46a(j)(2).

The adverse comments stated that the revised definition of ''boiler operating day'' and the inclusion of the 40 CFR part 75 data substitution requirement are independent of the amendments addressing the compliance procedures for duct burners. The commenters stated that these provisions are inconsistent with existing subpart Da procedures and their potential impacts were not analyzed or discussed in the proposal. On reviewing the relevant adverse comments, we agreed with their conclusion that these provisions are inconsistent with existing provisions in subpart Da and independent of the provisions addressing the compliance procedures for duct burners. Section 60.47a(c)(2) states that, although 40 CFR part 75 monitors can be used for subpart Da compliance, 40 CFR part 75 missing data and bias adjustment procedures shall not be used. As for the revised definition of ''boiler operating day,'' § 60.47a(f) requires data to be collected for at least 18 hours in a ''boiler operating day.'' The proposed revised definition of a ''boiler operating day'' is inconsistent with this requirement. Therefore, we are withdrawing the revised definition of ''boiler operating day'' and § 60.46a(j)(2) which contained the requirement for substituting data under 40 CFR part 75.

Based on the adverse comment received, we are amending subpart Da to add a revised § 60.46a(j)(2) which will become effective on June 11, 2001 as