Guidance for Industry

Donors of Blood and Blood Components: Notification of Donor Deferral

Small Entity Compliance Guide

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit written comments on this guidance at anytime to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. You should identify all comments with the Docket no. FDA-1998-N-1016 (formerly Docket no. 1998N-0607).

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or email ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
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Contains Nonbinding Recommendations

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I. INTRODUCTION

The Food and Drug Administration (FDA) has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121). According to the Small Business Administration, a "small business" within the blood industry is an enterprise with $10 million in average annual receipts.[1] This guidance is intended to help you, a small entity that collects blood or blood components for transfusion or for further manufacturing (blood or blood components), better understand and comply with the regulatory framework set forth in Title 21 Code of Federal Regulations 630.6 (21 CFR 630.6). This provision requires you to make reasonable attempts to notify donors, including autologous donors, that they are deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as required by 21 CFR 610.41, or determined not to be suitable for donation due to failure to satisfy suitability criteria under 21 CFR 640.3 or 21 CFR 640.63. This provision also requires you 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).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

[1] http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf (accessed May 26, 2011).

II. BACKGROUND

This guidance document provides information regarding 21 CFR 630.6 (§ 630.6)[2], which requires establishments that collect blood or blood components to 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 with a communicable disease agent(s) under 21 CFR Part 610 or determined not to be suitable for donation based on failure to satisfy suitability criteria under 21 CFR Part 640. We note that while this guidance is specifically designed to be of use to small entities that collect blood or blood components, the requirements and recommendations in this guidance are applicable to all entities that collect blood or blood components, regardless of size.

III. NOTIFICATION REQUIREMENTS

A. What are the Notification Requirements under § 630.6?

Under § 630.6(a), you 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 21 CFR 610.41 (§ 610.41) or who has been determined not to be suitable as a donor based on suitability criteria under 21 CFR 640.3 or 21 CFR 640.63. In addition, under § 630.6(d), you also must make reasonable attempts to notify an autologous donor's referring physician when an autologous donor has been deferred. These requirements are designed to reduce the risk of transmission of communicable disease from the use of blood and blood components. You are not required to use these notification procedures to notify donors that you have voluntarily deferred for medical reasons beyond those required in § 630.6 (66 FR 31165 at 31167).

Under § 630.6(b), you must provide the following information to a donor that was deferred or determined not to be suitable for donation:

- That the donor is deferred or determined not to be suitable for donation and the reason for that decision;
- Where appropriate, the types of donation of blood or blood components that the donor should not donate in the future;
- 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,

[2] FDA published the final rule on the general requirements for donor notification in the *Federal Register* of June 11, 2001 (66 FR 31165). We note that in the *Federal Register* of November 8, 2007, FDA proposed modifications to some of the requirements described in this guidance in a proposed rule entitled "Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use" (72 FR 63416).

including results of supplemental (i.e., additional, more specific) tests as required in § 610.40(e); and
- Where appropriate, information concerning medical followup and counseling.

B. How Should You Notify Donors under § 630.6?

Under § 630.6(c), 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. You have the flexibility to choose the manner in which you notify the donor, including the method by which you protect donor confidentiality. You may choose to notify: (1) in person at the time of the actual deferral; (2) in person at the donor's first return visit; (3) by phone; or (4) by mail (e.g., regular mail, certified mail, registered mail, etc.). You also may notify donors with generic letters, provided that this method of notification provides all of the required information. However, you may need to supplement a generic letter on a case-by-case basis with information specific to the donor. Alternatively, you may also choose to send letters to donors requesting that they return for direct notification (66 FR 31165 at 31170). In any event, the personnel performing this activity must be adequately trained as required in 21 CFR 606.20 (§ 606.20).

You must make reasonable attempts to contact the donor who has been deferred until you succeed in notifying the donor or until it is clear that further attempts will not be successful in accordance with your written Standard Operating Procedures (SOPs) (§ 606.100(b)(20)). If one method of notifying the donor is unsuccessful, you may need to use a different method of notification. For example, if you mail a donor notification letter and it is returned unopened, you may need to use a different method of notification, such as phone the donor and either notify the donor at that time or ask for a correct address in order to resend the letter. Alternatively, you could also try checking the donor's record (see § 606.160(b)(1)(x)) to verify the donor's address or searching the local phone book or the internet to verify the correct address and then resend the notification letter (66 FR 31165 at 31170).

FDA is aware of varying State requirements concerning notification of State health authorities of a donor's positive test results, as opposed to 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 you make reasonable attempts to notify the donor who has been deferred directly of all test results that were the basis for deferral and that the donor be given information, where appropriate, concerning medical followup and counseling. The requirements contained in § 630.6 are in addition to, and do not conflict with, State requirements (66 FR 31165 at 31168).

C. Are You Required to Notify Donors of the Results of Supplemental Tests under § 630.6?

The regulations require that the donor who has been deferred be notified of both the screening and supplemental (i.e., additional, more specific) test results (§ 630.6(a)). As a general matter, to minimize the impact on small entities while continuing to protect the public health, the agency does not require donor notification until after the results of the approved supplemental testing are available, where it is reasonable to assume that these test results will be available within the 8-week notification time frame (66 FR 31165 at 31171 & 31173). When the approved supplemental test results will not be available within the 8-week time period, you must make reasonable attempts to notify the donor who has been deferred based on the results of screening tests for evidence of infection with a communicable disease agent(s) (§ 630.6(a)). Note that in such instances, you would then be required to notify the donor of the results of the supplemental testing when they become available (§ 630.6(a)).

Because an approved supplemental test for human T-lymphotropic virus (HTLV), types I and II, and anti-hepatitis B core (anti-HBc) is not available at this time, you are not required to notify or defer donors with a single reactive test result for HTLV, types I and II, or anti-HBc. We believe it is appropriate that blood 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 § 610.40(h)(1), the allogeneic donation that tests reactive must not be shipped or transfused, even though the donor remains in the donor pool until the donor tests reactive on a second occasion (66 FR 31165 at 31169). We note that it remains our intent that if licensed supplemental tests for HTLV, types I and II, or anti-HBc are approved, you would be required to defer donors after a single reactive test result regardless of the results of the supplemental (additional, more specific) tests, and to notify the donor of both the screening and supplemental test results as prescribed in § 630.6(b) (66 FR 31165 at 31169).

D. What are the Notification Requirements as to Autologous Donors under § 630.6?

In recognition of how an autologous donation may be a medically ordered procedure, you also must make reasonable attempts to notify the autologous donor's referring physician that the donor has been deferred based on test results and the reason for that decision under § 630.6(d).

You must make reasonable attempts to notify the autologous donor and his or her referring physician within 8 weeks after determining that the donor is deferred or determined not to be suitable for donation (§ 630.6(c) and § 630.6(d)(2)). The information you must provide to the autologous donor under § 630.6(a) is the

same information that you are required to provide to an allogeneic donor and is described in section III.A. of this guidance document. In addition, under § 630.6(d)(1), you must provide the following information to the autologous donor's referring physician:

- 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 and the reason for that decision;
- Where appropriate, the types of donation of blood or blood components that the autologous donor should not donate in the future; and
- The results of tests for evidence of infection due to communicable disease agent(s) that were a basis for deferral under § 610.41, including results of supplemental (i.e., additional, more specific) tests as required under § 610.40(e).

IV. RECORDKEEPING REQUIREMENTS

You are required to obtain and keep a record of an address where the donor may be reached within 8 weeks after donation (§ 606.160(b)(1)(x)). Under § 606.160(b)(1)(ix), you also must document that you have successfully notified a donor who has been deferred, including an autologous donor, or when you are unsuccessful, that you have made reasonable attempts to notify the donor if the initial attempt at notification fails. Furthermore, under § 606.160(b)(1)(xi), you must maintain records of notification of the referring physician of an autologous donor who has been deferred, including appropriate followup if the initial notification attempt fails.

V. STANDARD OPERATING PROCEDURES

As required in § 606.100(b)(20), you must prepare written SOPs for donor notification and autologous donor referring physician notification, including procedures for the appropriate followup if the initial attempt at notification fails. You should also consider writing your SOPs to include instructions for the documentation of reasonable attempts, including unsuccessful attempts, made to contact donors who have been deferred and the referring physician of autologous donors who have been deferred. Furthermore, you should consider including instructions for the documentation of the reason for the deferral. We note that under § 606.100(b), these SOPs must be maintained and must include all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components. We further note that these SOPs must be available to personnel for use in the areas where these procedures are performed (§ 606.100(b)).