DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 607, 610, and 640

[Docket No. 2007N–0264]

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection. This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments by October 30, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2007N–0264, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under Electronic Submissions.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comments and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule. We are publishing the direct final rule because the rule is noncontroversial, and we do not anticipate that it will receive any significant adverse comments.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document, before the effective date of the direct final rule, confirming that the direct final rule will go into effect on February 19, 2008. Additional information about direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

II. Legal Authority

FDA is proposing to issue this new rule under the biological products and communicable diseases provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262–264), and the drugs, devices, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 351–353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled, and to prevent the introduction, transmission, and spread of communicable disease.

III. Highlights of Proposed Rule

FDA is proposing to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. We are also issuing these amendments as a direct final rule because we have concluded that they are noncontroversial and that there is little likelihood that there will be comments opposing the rule. Any comment recommending additional changes to these regulations will not be considered

to be a ''significant adverse comment'' unless the comment demonstrates that the change being made in the direct final rule represents a major departure from current regulations or accepted industry standards, or cannot be implemented without additional amendments to the regulation. Below we identify each of the changes included in this proposed rule.

We are proposing to amend 21 CFR 606.3(i) by revising the definition of ''processing'' to mean any procedure employed after collection and before ''or after'' compatibility testing of blood. The current regulation states that processing means any procedure employed after collection and before compatibility testing of blood. Because blood components occasionally are further processed after compatibility testing has been performed, we are proposing this revision to the definition.

We are proposing to amend 21 CFR 607.65(f) by removing the words ''approved for Medicare reimbursement and'' and replacing with the words ''that is certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and which are''. As a result of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the implementing regulations adopted by the Centers for Medicaid and Medicare Services (CMS), the inspection regime relied on in a 1983 Memorandum of Understanding (MOU) between FDA and the Health Care Financing Administration (HCFA), now CMS, will be modified. Under the CLIA program, clinical laboratories must be surveyed by CMS (either directly or through a State survey agency), unless they are located in a CLIA-approved State, or are accredited by a CMS-approved accreditation organization. CLIA regulations apply to clinical laboratories regardless of whether or not the laboratories seek Medicare participation. FDA is proposing to amend this regulation to make it consistent with updates in the CMS regulations.

We are proposing to amend 21 CFR 610.53(c) by revising the dating period in the table for Platelets, Red Blood Cells Deglycerolized, and Red Blood Cells Frozen. Although the current recommended dating period would remain unchanged for Platelets and Red Blood Cells Deglycerolized, we are proposing to add that a different dating period could apply for these products if so specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research (CBER). This change would allow for flexible dating periods depending on the type of collecting, processing, and storage system used. In addition, under Red Blood Cells Frozen, we are proposing to revise the dating period from 3 years to 10 years, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER. This change would allow for flexible dating periods depending on the type of collecting, processing, and storage system used.

Under § 640.4(h) (21 CFR 640.4(h)), we are proposing to revise the temporary storage temperature for blood that is transported from the donor center to the processing laboratory. We are proposing a range between 1 and 10° C until the blood arrives at the processing laboratory. We are proposing this revision to be consistent with 21 CFR 600.15 which allows for shipping temperatures of Whole Blood to be from 1 to 10° C, and for consistency with current industry practice. In addition, we are proposing to revise the applicability of this requirement to Whole Blood unless it is to be further processed into another component, such as Platelets or Red Blood Cells Leukocytes Reduced. The current regulation applies only to Whole Blood unless the blood is to be used as a source for Platelets. This change would clarify that processing Whole Blood into other components, in addition to Platelets, is acceptable. For Whole Blood that is to be processed into another component, we are proposing that the blood must be stored in an environment maintained at a temperature range that is specified for that component in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER. We are also proposing to replace the term donor ''clinic'' with donor ''center'' for consistency with § 640.4(b) and current terminology.

We are proposing to remove and reserve § 640.21(b) (21 CFR 640.21(b)) because this provision is obsolete, as well as proposing to remove the reference to plasmapheresis in 21 CFR 640.20(b). Improvements in technology now allow establishments to collect Platelets by automated methods eliminating the need for the collection of platelets by manual plasmapheresis. Currently, establishments may collect Platelets by automated platelet-specific apheresis collection procedures. We are proposing to amend § 640.21(c) by adding that plateletpheresis donors must meet the criteria for suitability as prescribed in 21 CFR 640.3 and 640.63(c)(6), or as described in an approved biologics license application (BLA) or an approved supplement to a BLA, and that informed consent must be obtained as prescribed in 21 CFR 640.61. This revision would clarify that registered facilities must follow the suitability requirements for plateletpheresis donors.

We are proposing to remove and reserve § 640.22(b) (21 CFR 640.22(b)) because this regulation is obsolete. As previously mentioned, improvements in technology now allow establishments to collect Platelets by automated methods, eliminating the need for the collection of platelets by plasmapheresis. Currently, establishments may collect Platelets by automated platelet-specific apheresis collection procedures. We are proposing to amend § 640.22(c) by adding that if plateletpheresis is used, the procedure for collection must be as prescribed in 21 CFR 640.62—*Medical supervision*; 21 CFR 640.64—*Collection of blood for Source Plasma*; and 21 CFR 640.65—*Plasmapheresis*, or as described in an approved biologics license application or an approved supplement to a BLA. This revision would clarify that registered facilities must follow the collection of source material requirements for plateletpheresis donors.

We are proposing to amend 21 CFR 640.24(a) to allow Platelets to be pooled under certain circumstances. That is, Platelets may be pooled if such processing is specified in the directions for use for the blood collecting, processing, and storage system for approved such use by the Director, CBER. We are proposing to amend the regulation to provide flexibility depending on the type of collecting, processing, and storage system used.

We are proposing to amend 21 CFR 640.25(b)(2) by revising the pH level from ''6.0'' to ''6.2'' for consistency with current industry practice. Studies have shown that a lower pH may adversely affect platelet function (Refs. 1 and 2).

We are proposing to amend 21 CFR 640.30(a) by revising the term ''product,'' to ''component,'' for consistency with current terminology of the proper name. We are also proposing to add an alternative definition of Plasma, namely, ''The fluid portion of human blood intended for intravenous use which is prepared by apheresis methods as specified in the directions for use for the blood collecting, processing, and storage system including closed and open systems.'' We are proposing this change because

Plasma is now collected by other methods, such as apheresis collection, in addition to being collected as a byproduct of Whole Blood collection.

We are proposing to amend 21 CFR 640.32(a) to add that a different storage temperature may be used for Whole Blood intended for further manufacturing into Plasma, Fresh Frozen Plasma, or Liquid Plasma. Any different storage temperature would be specified in the directions for use for the blood collecting, processing, and storage system. This change would allow for flexible storage temperatures depending on the particular type of system used.

We are proposing to amend 21 CFR 640.34(b) by adding the phrase ''or collected by an apheresis procedure'' in the second sentence to clarify that this section also applies to plasma collected by aphersis procedures. We would require that fresh frozen plasma using the apheresis procedure be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor's tissue.

We are proposing to amend § 640.64(b) (21 CFR 640.64(b)) by removing the second sentence that states, ''The amount of anticoagulant required for the quantity of blood to be collected shall be in the blood container when it is sterilized.'' We are proposing to remove this sentence because of technological advances. Now, the anticoagulant does not always have to be in the collection set. The anticoagulant can be connected by a ''sterile docking'' procedure or attached separately, as is the case with automated apheresis collection. We are also proposing to amend § 640.64(c) by removing the specific anticoagulant solution formulas and indicating that the anticoagulant solutions must be compounded and used according to a formula approved by the Director, CBER. We have determined that it is unnecessary to provide specific formulae for anticoagulant solutions in the regulations, and that manufacturers should be able to use any anticoagulant approved by the FDA for such use by the manufacturer.

We have also revised the above regulations, where applicable, by using ''must'' or ''is'' instead of ''shall,'' depending on the circumstances. We have made these revisions for plain language purposes. These editorial changes are for clarity only and do not change the substance of the requirements. We will continue to make these changes in other applicable regulations as they are revised in future rulemakings. In addition, we will continue to make the change from ''product'' to ''component'' in other applicable regulations as they are revised in future rulemakings.

IV. Analysis of Impacts

A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Act of 1995

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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 agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule amendments have no compliance costs and do not result in any new requirements, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1–year expenditure that would meet or exceed this amount.

B. Environmental Impact

The agency has determined, under 21 CFR 25.31(h), 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.

C. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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 proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

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

1. Scott Murphy, ''Platelet Storage for Transfusion,'' *Seminars in Hematology*, 22(3): 165–177, July 1985.

2. L. Dumont and T. VandenBroeke, ''Seven-Day Storage of Apheresis Platelets Report of an In Vitro Study,'' 43: 143–150, *Transfusion*, February 2003.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 607

Blood.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated by the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 606, 607, 610, and 640 be amended as follows:

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

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

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.3 is amended by revising paragraph (i) to read as follows:

§ 606.3 Definitions.

* * * * *

(i) *Processing* means any procedure employed after collection and before or after compatibility testing of blood, and includes the identification of a unit of donor blood, the preparation of components from such unit of donor blood, serological testing, labeling and associated recordkeeping.

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PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

3. The authority citation for 21 CFR part 607 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

4. Section 607.65 is amended by revising the first sentence in paragraph (f) to read as follows:

§ 607.65 Exemptions for blood product establishments.

* * * * *

(f) Transfusion services which are a part of a facility that is certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and which are engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components. * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

6. Section 610.53 is amended in paragraph (c) in the table by revising the entries for Platelets, Red Blood Cells Deglycerolized, and Red Blood Cells Frozen to read as follows:

§ 610.53 Dating periods for licensed biological products.

* * * * *

(c) * * *

A	B	C	D
Product	Manufacturer's storage period 1 to 5° C (unless otherwise stated).	Manufacturer's storage period 0° C or colder (unless otherwise stated).	Dating period after leaving manufacturer's storage when stored at 2 to 8° C (unless otherwise stated)
*	*	*	*	*	*	*
Platelets	Not applicable	do	72 hours from time of collection of source blood, provided labeling recommends storage at 20 to 24° C or between 1 and 6° C, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research (CBER).
*	*	*	*	*	*	*
Red Blood Cells Deglycerolized	do	do	24 hours after removal from storage at 65° C or colder, provided labeling recommends storage between 1 and 6° C, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.
Red Blood Cells Frozen	do	do	10 years from date of collection of source blood, provided labeling recommends storage at 65° C or colder, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.

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PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

7. 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.

8. Section 640.4 is amended by revising paragraph (h) to read as follows:

§ 640.4 Collection of the blood.

* * * * *

(h) *Storage.* Whole blood must be placed in storage at a temperature between 1 and 6° C immediately after collection unless the blood is to be further processed into another component or the blood must be transported from the donor center to the processing laboratory. If transported, the blood must be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously at a temperature range between 1 and 10° C until arrival at the processing laboratory. At the processing laboratory, the blood must be stored at a temperature between 1 and 6° C. Blood from which a component is to be prepared must be held in an environment maintained at a temperature range specified for that

component in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.

9. Section 640.20 is amended by revising paragraph (b) to read as follows:

§ 640.20 Platelets.

* * * * *

(b) *Source.* The source material for Platelets is plasma which may be obtained by whole blood collection or by plateletpheresis.

10. Section 640.21 is amended by removing and reserving paragraph (b) and revising paragraph (c) to read as follows:

§ 640.21 Suitability of donors.

* * * * *

(b) [Reserved]

(c) Plateletpheresis donors must meet the criteria for suitability as prescribed in §§ 640.3 and 640.63(c)(6), or as described in an approved biologics license application (BLA) or an approved supplement to a BLA. Informed consent must be obtained as prescribed in § 640.61.

11. Section 640.22 is amended by removing and reserving paragraph (b) and revising paragraph (c) to read as follows:

§ 640.22 Collection of source material.

* * * * *

(b) [Reserved]

(c) If plateletpheresis is used, the procedure for collection must be as prescribed in §§ 640.62, 640.64 (except paragraph (c)), and 640.65, or as described in an approved biologics license application (BLA) or an approved supplement to a BLA.

* * * * *

12. Section 640.24 is amended by revising paragraph (a) to read as follows:

§ 640.24 Processing.

(a) Separation of plasma and platelets and resuspension of the platelets must be in a closed system. Platelets must not be pooled during processing unless the platelets are pooled as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research.

* * * * *

§ 640.25 [Amended]

13. Section 640.25 is amended in paragraph (b)(2) by removing ''6.0'' and adding in its place ''6.2''.

14. Section 640.30 is amended by revising paragraph (a) to read as follows:

§ 640.30 Plasma.

(a) *Proper name and definition.* The proper name of this component is Plasma. The component is defined as:

(1) The fluid portion of one unit of human blood intended for intravenous use which is collected in a closed system, stabilized against clotting, and separated from the red cells; or

(2) The fluid portion of human blood intended for intravenous use which is prepared by apheresis methods as specified in the directions for use for the blood collecting, processing, and storage system including closed and open systems.

* * * * *

15. Section 640.32 is amended by revising paragraph (a) to read as follows:

§ 640.32 Collection of source material.

(a) Whole Blood must be collected, transported, and stored as prescribed in § 640.4. When whole blood is intended for Plasma, Fresh Frozen Plasma, and Liquid Plasma, until the plasma is removed, the whole blood must be maintained at a temperature between 1 and 6° C or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluations and Research. Whole blood intended for Platelet Rich Plasma must be maintained as prescribed in § 640.24 until the plasma is removed. The red blood cells must be placed in storage at a temperature between 1 and 6° C immediately after the plasma is separated.

* * * * *

16. Section 640.34 is amended by revising the second sentence in paragraph (b) to read as follows:

§ 640.34 Processing.

* * * * *

(b) *Fresh Frozen Plasma.* * * * The plasma must be separated from the red blood cells or collected by an apheresis procedure, and placed in a freezer within 8 hours or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system, and stored at 18° C or colder.

* * * * *

17. Section 640.64 is amended by revising paragraphs (b) and (c) to read as follows:

§ 640.64 Collection of blood for source plasma.

* * * * *

(b) *Blood containers.* Blood containers and donor sets must be pyrogen-free, sterile, and identified by lot number.

(c) *The anticoagulant solution.* The anticoagulant solution must be sterile and pyrogen-free. Anticoagulant solutions must be compounded and used according to a formula that has been approved for the applicant by the Director, Center for Biologics Evaluation and Research.

* * * * *

Dated: July 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–15942 Filed 8–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 53 and 301

[REG–142039–06; REG–139268–06]

RIN 1545–BG18; 1545–BG20

Excise Taxes on Prohibited Tax Shelter Transactions and Related Disclosure Requirements; Disclosure Requirements With Respect to Prohibited Tax Shelter Transactions; Requirement of Return and Time for Filing; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Corrections to notice of proposed rulemaking by cross-reference to temporary regulations and notice of proposed rulemaking.

SUMMARY: This document contains corrections to notice of proposed rulemaking by cross-reference to temporary regulations (REG–142039–06) and notice of proposed rulemaking (REG–139268–06) that were published in the **Federal Register** on Friday, July 6, 2007 (72 FR 36927) providing guidance under 4965 of the Internal Revenue Code and relating to entity-level and manager-level excise taxes with respect to prohibited tax shelter transactions to which tax-exempt entities are parties; §§ 6033(a)(2) and 6011(g), relating to certain disclosure obligations with respect to such transactions; and §§ 6011 and 6071, relating to the requirement of a return and time for filing with respect to section 4965 taxes.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Galina Kolomietz, (202) 622–6070, or Michael Blumenfeld, (202) 622–1124 (not toll-free numbers). For questions specifically relating to qualified pension plans, individual retirement accounts, and similar tax-favored savings arrangements, contact Dana Barry, (202) 622–6060 (not a toll-free number).