

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DPM

Food and Drug Administration

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21 CFR Parts 606, 607, 610, and 640

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[Docket No. FDA-2008-N-0067]

Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Confirmation of Effective Date and Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date and technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of February 19, 2008, for the direct final rule that appeared in the **Federal Register** of August 16, 2007 (72 FR 45883). The direct final rule amends 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and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. In addition, FDA is making technical amendments to the biologics regulations in response to comments received on the direct final rule.

DATES: The effective date for the regulation is confirmed as February 19, 2008. The effective date of the technical amendment is also February 19, 2008.

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

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SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 16, 2007 (72 FR 45883), FDA solicited comments concerning the direct final rule for a 75-day period ending October 30, 2007. FDA stated that the effective date of the direct final rule would be on February 19, 2008, 6 months after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA received several letters of comment on the direct final rule; however, FDA did not receive any significant adverse comments. Therefore, FDA is confirming the effective date of the direct final rule and making two technical amendments in response to comments received. Comments were received from private industry, an individual, organizations representing the blood industry, and an employee of the Food and Drug Administration. The comments received and FDA's responses to the comments are discussed below as follows:

Two comments stated that under paragraph (c) of 21 CFR 610.53, there was an error in a temperature listed in the table under Red Blood Cells Deglycerolized and Red Blood Cells Frozen.

FDA agrees. In the **Federal Register** of September 24, 2007 (72 FR 54208), FDA issued a notice to correct a typographical error in the codified section of the direct final rule. The table in paragraph (c) of section 610.53 was corrected by replacing 65°C with -65°C.

One comment requested clarification of the proposed change in wording from "toward" to "at" concerning the specified temperature range under 21 CFR 640.4(h) because coolers do not have the capacity to maintain a temperature range between 1 and 10°C.

FDA agrees with the comment and therefore, is revising the regulation to use "toward" rather than "at".

One comment requested that under 21 CFR 640.24(d) the pH be revised from “not less than 6.0” to “not less than 6.2” to be consistent with the change in 21 CFR 640.25(b)(2) (§ 640.25(b)(2)) and with industry practice .

Because both of these provisions refer to the same pH requirement, FDA agrees and is revising 21 CFR 640.24(d) as requested.

One comment agreed with the change in pH under § 640.25(b)(2) but stated that there was no mention of the number of units that must meet this requirement and therefore the assumption is that 100 percent of the units must meet the requirement which they believe is unachievable.

We believe that the four units we require to be tested for quality control purposes under § 640.25(b) must meet the criteria listed under this regulation. However, FDA recently issued a document entitled “Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods,” dated December 2007 (December 17, 2007; 72 FR 71418). In this guidance, we provide recommendations on quality control monitoring. Therefore, no additional changes are warranted.

Two comments requested that FDA revise the definition under 21 CFR 640.30(a) to include “for intravenous or further manufacturing use” to facilitate use of plasma for further manufacturing use that has been collected concurrently with the collection of another blood component by apheresis. In addition, the comments requested that 21 CFR 640.34 and other provisions in the regulations be revised and harmonized to allow interchangeability of the plasma from intravenous use to manufacturing use after blood collection.

FDA presently has this issue under consideration and may address this in future rulemaking, if warranted. This comment is beyond the scope of this rulemaking.

One comment requested that FDA provide the rationale for the revision to 21 CFR 640.34(b) requiring fresh frozen plasma collected by an apheresis procedure to be prepared from blood collected by single uninterrupted venipuncture, and why it was differentiated from other components collected by apheresis. The comment also questioned whether the current practice of using a sterile connecting device to attach a sterile needle in the event of blood flow interruption would be prohibited in the future.

The rationale for requiring blood and blood components, including fresh frozen plasma collected by an apheresis procedure, to be collected by a single uninterrupted venipuncture is to help ensure minimal tissue damage which could activate the coagulation cascade. This is also a requirement for Platelet collection. Under 21 CFR 640.22(d), the regulation states that Platelet phlebotomy shall be performed by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor's tissue. FDA does not anticipate, in the near future, any change in the policy for using a sterile connecting device to attach a sterile needle to a collection set in the event of a blood flow interruption.

List of Subjects

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, 21 CFR part 640 is amended as follows:

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

- 1. 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.

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

§ 640.4 Collection of the blood.

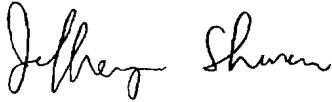
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(h) *Storage.* Whole Blood must be placed in storage at a temperature between 1 and 6 °C immediately after collection unless the blood is to be further processed into another component or the blood must be transported from the donor center to the processing laboratory. If transported, the blood must be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward 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.

§ 640.24 [Amended]

- 3. Section 640.24 is amended in the first sentence of paragraph (d) by removing “6.0” and adding in its place “6.2”.

Dated: 2-1-08
February 1, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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