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Certifier K. CLAWSON
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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; Correction

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9-19-07

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; correction.

SUMMARY: The Food and Drug Administration is correcting a direct final rule that appeared in the **Federal Register** of August 16, 2007 (72 FR 45883). That document amended 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and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. A proposal was published as a companion document to the direct final rule in the same issue of the **Federal Register** (August 16, 2007, 72 FR 45993). Both documents published with a typographical error in the codified section. This document corrects the error in the direct final rule. Elsewhere in this issue of the **Federal Register** we are correcting the error in the proposed rule.

DATES: ^{This correction} The ~~direct final rule~~ is effective February 19, 2008. Submit written or electronic comments on the direct final rule by October 30, 2007. If we receive no significant adverse comments during the specified comment period, we intend to publish a confirmation document on or before the effective date of the direct final rule confirming that the direct final rule will go into effect

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on February 19, 2008. If we receive any significant adverse comments during the comment period, we intend to withdraw the direct final rule before its effective date by a notice published in the **Federal Register**.

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~~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.

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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

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comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of the direct final rule (72 FR 45883 at 45886).

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:

For information regarding this correction: Joyce Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

For information regarding the direct final rule: 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: In FR Doc. E7-15943, appearing on page 45883, in the **Federal Register** of Thursday, August 16, 2007, the following correction is made:

8610.53 [Corrected]

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1. On page 45887, in the amendment to § 610.53 *Dating periods for licensed biological products*, in the table in paragraph (c), “65° C” is corrected to read “-65° C” everywhere it appears.

Dated: 9/17/07
September 17, 2007.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

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