

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 606

[Docket No. 2003N-0211]

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Certifier A. Corbin

Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that proposed to revise the labeling and storage requirements for certain human blood and blood components, including Source Plasma (proposed labeling and storage rule). The proposed rule appeared in the **Federal Register** of July 30, 2003 (68 FR 44678). The proposed regulation included a paragraph that FDA did not intend to publish. This document corrects that error by removing the incorrect paragraph from the proposed rule.

DATES: Submit written or electronic comments on the proposed rule by October 28, 2003.

ADDRESSES: Submit written comments 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.fda.gov/dockets/ecomments>.

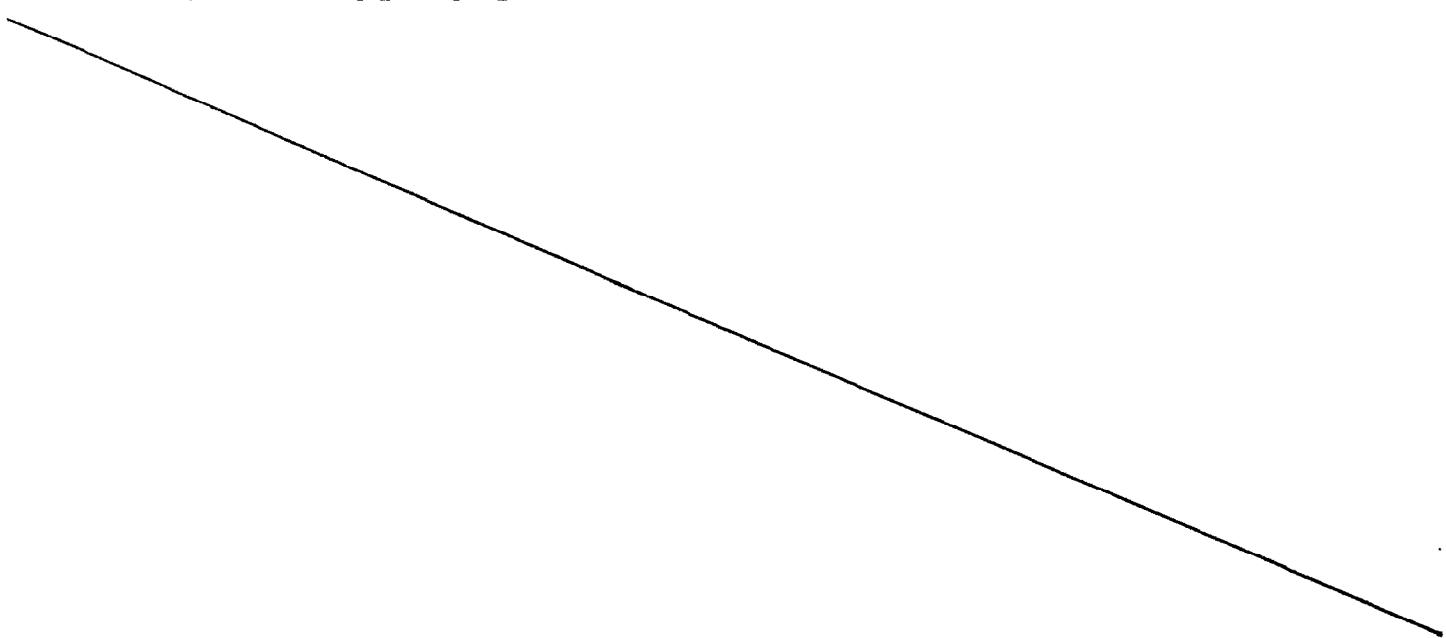
FOR FURTHER INFORMATION CONTACT: Sharon Carayiannis, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: The proposed rule that published in the **Federal Register** of July 30, 2003, inadvertently included § 606.121(c)(13) in the proposed text of the regulation (68 FR 44678 at 44686). As discussed in the proposed labeling and storage rule (68 FR 44678 at 44682), FDA issued a related proposed rule entitled “Bar Code Label Requirements for Human Drug Products and Blood” (proposed bar code rule) in the **Federal Register** of March 14, 2003 (68 FR 12499). The proposed bar code rule would amend § 606.121(c)(13) to require certain human drug and biological product labels to bear bar codes and also would require the use of machine-readable information on container labels for blood and blood components intended for transfusion. FDA did not intend to propose to revise § 606.121(c)(13) in the proposed labeling and storage rule, and the agency is removing that paragraph to eliminate any confusion that might occur.

In FR Doc. 03–19289, appearing on page 44678, in the **Federal Register** of July 30, 2003, the following correction is made:

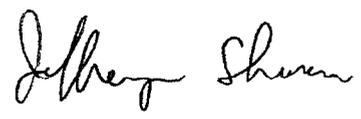
§ 606.121 [Corrected]

1. On page 44686, in the third column, § 606.121 *Container label* is corrected by removing paragraph (c)(13).



Dated: 10. 20. 03
October 20, 2003.

cb0339



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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