

reference this action with the Unified Agenda.

Unfunded Mandates Reform Act

The Department will analyze any action that might be proposed for the purpose of the Unfunded Mandates Reform Act of 1995 to assess whether a rulemaking would impose unfunded mandates.

National Environmental Policy Act

The Department will analyze any action that might be proposed for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) to determine whether there would be any effect on the quality of the environment.

(Authority: 49 U.S.C. Chapters 401, 411, 417; 14 CFR Part 204.)

Dated: July 24, 2003.

Michael W. Reynolds,

Acting Assistant Secretary for Aviation and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 606, 610, and 640

[Docket No. 2003N–0211]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the labeling and storage requirements for certain human blood and blood components, including Source Plasma, by combining, simplifying, and updating specific regulations applicable to container labeling and instruction circulars, and the shipping and storage temperatures for frozen noncellular blood components. This proposed rule would facilitate the use of a labeling system using machine-readable information that would be acceptable as a replacement for the “ABC Codabar” system for labeling blood and blood components. FDA is taking this action as part of its “Blood Initiative” to comprehensively review and, as necessary, revise its regulations, policies, guidances, and procedures related to the licensing and regulation of

blood products. This proposed rule is intended to help ensure the continued safety of the blood supply, and to help ensure consistency in container labeling and storage temperatures.

DATES: Submit written or electronic comments on the proposed rule by October 28, 2003. See section VIII of this document for the proposed effective date of a final rule based on this document.

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 A. Carayannis, 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. Background

A. Development of the International Society for Blood Transfusion (ISBT) 128

In the **Federal Register** of August 30, 1985 (50 FR 35472), FDA published a notice of availability entitled “Guideline for the Uniform Labeling of Blood and Blood Components,” which described the uniform container label for blood and blood components. The standard labels for blood and blood components recommended in the guideline incorporated barcode symbology known as “ABC Codabar.”

In August 1989, the ISBT, an organization established to promote and maintain a high level of ethical, medical, and scientific standards in blood transfusion medicine and science throughout the world, recognized that “ABC Codabar,” the first barcoding system adopted by the health care industry, was becoming outdated and initiated the design of a new system using the barcode symbology known as Code 128 (identified hereafter as ISBT 128).

Currently, under § 606.121(c)(13) (21 CFR 606.121(c)(13)), the container label for blood and blood components may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research (CBER). On March 23, 1995, FDA asked the Blood Products Advisory Committee (BPAC) whether FDA should support conversion from the “ABC Codabar” system to the ISBT 128 system. BPAC

voted in favor of FDA supporting the transition to the new barcoding system. The change to ISBT 128 was also supported by the Department of Defense (DoD), and by the blood industry including America’s Blood Centers (ABC), American Association of Blood Banks (AABB), and American National Red Cross (ARC). In December 1996, the International Council for Commonality in Blood Bank Automation (ICCBBA) held an ISBT 128 Consensus Conference in Washington, DC, to provide an opportunity for dialogue among the affected industry groups and FDA. Although consensus was obtained for use of ISBT 128, some participants expressed concerns regarding implementation timeframes and costs of implementation to hospital transfusion services. However, the updated symbology used in ISBT 128 has numerous advantages over the “ABC Codabar.” In addition to other reasons, the conversion to ISBT 128 was supported because ISBT 128 is more secure, allows more flexibility in coding highly variable information, uses double-density coding to allow more information to be encoded in a limited space, and can be interpreted by some of the barcode readers used with “ABC Codabar.”

The ICCBBA, including representatives from ABC, AABB, ARC, and DoD, developed and submitted to FDA a draft document that recommended that ISBT 128 replace the “ABC” Codabar system used on blood and blood component labels in the United States. ICCBBA recommended that the document entitled “United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128,” Version 1.2.0 (draft standard), serve as the basis for FDA guidance on blood and blood component labeling. On November 21, 1998, FDA made a copy of the draft standard available on its Web site for public comment. In the **Federal Register** of November 27, 1998 (63 FR 65600), FDA announced the availability of the draft standard and requested public comment on both the use of ISBT 128 and timeframes for implementation. The ICCBBA revised the draft standard in response to public comment and submitted to FDA the revised document, “United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128,” Version 1.2.0, dated November 1999 (the “Version 1.2.0 Standard”).

FDA reviewed the draft standard, the comments received in response to the **Federal Register** notice of November 27, 1998, and the “Version 1.2.0 Standard,”