

and concluded that conformance to the "Version 1.2.0 Standard," prepared and revised by ICCBBA, would help facilitate the use of a uniform container label for blood and blood components. In the **Federal Register** of June 6, 2000 (65 FR 35944), FDA announced the availability of a final guidance entitled "Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components" dated June 2000, which recognizes as acceptable, except where inconsistent with the regulations, use of the "Version 1.2.0 Standard" prepared by ICCBBA, and the implementation of the ISBT 128 uniform labeling system. Although FDA finds the system acceptable, FDA has identified two inconsistencies between the "Version 1.2.0 Standard" and the current requirements of § 606.121(c)(2) and (e)(1)(ii). This proposed rule would delete the current requirement of § 606.121(c)(2) to include the FDA assigned registration number on blood and blood component labels. This revision is intended to provide establishments flexibility in using the registration number or other recognized donation facility identification numbers, such as the ISBT facility code (which includes machine-readable information), as the unique facility identifier. Additionally, this proposed rule would delete the current requirement of § 606.121(e)(1)(ii) that the anticoagulant precede the proper name. However, until the date a final rule resulting from this proposal becomes effective, if a manufacturer intends to follow the "Version 1.2.0 Standard" in lieu of current § 606.121(c)(2) or (e)(1)(ii), a manufacturer would seek an approval for exceptions or alternatives under § 640.120 (21 CFR 640.120). Once the application for an alternative is approved, a manufacturer may use the "Version 1.2.0 Standard" to produce labels that meet FDA's labeling requirements.

B. Changes to Storage and Shipping Temperatures

FDA has reviewed data concerning the storage and shipping temperatures of frozen noncellular blood components, e.g., Cryoprecipitated Antihemophilic Factor and Fresh Frozen Plasma. We have determined that the current requirements for storage and shipping temperatures should be updated to ensure potency of the blood components over time and to provide more flexibility in inventory management. Therefore, we are proposing to revise the current storage and shipping temperatures for frozen noncellular blood components, both for transfusion and for further manufacturing use, to guard against degradation of the heat labile clotting factors. The proposed changes in shipping and storage temperatures are consistent with published data and current industry practice (Ref. 1).

II. Highlights of the Proposed Rule

FDA is proposing to remove, simplify, or update specific labeling regulations applicable to blood and blood components to be more consistent with current practices and to remove any unnecessary or outdated requirements. FDA is proposing to consolidate the labeling requirements for blood and blood components intended for transfusion and for blood and blood components intended for further manufacturing use. FDA is proposing to revise specific regulations to facilitate the use of a uniform container label for blood and blood components in the United States and internationally and to remove any inconsistency between the "Version 1.2.0 Standard" and the Federal regulations at § 606.121. The proposed rule would facilitate the use of a labeling system using the ISBT 128 machine-readable data. In addition, the proposal would facilitate the use of new labeling systems that may be developed in the future.

The proposed changes would also simplify the regulations by consolidating the regulations for labeling blood and blood components,

including Source Plasma, into one section, making it unnecessary for blood establishments to refer to several sections of the regulations to find applicable labeling standards.

In addition to moving certain regulations to § 606.121, FDA is also proposing to revise some of the labeling provisions regarding storage and shipping temperatures for frozen noncellular blood components in proposed § 640.70(a)(3) and (b). FDA is proposing to revise storage and shipping temperatures in current §§ 600.15, 610.53, 640.34, 640.54, 640.69, and 640.76, (21 CFR 600.15, 610.53, 640.34, 640.54, 640.69, and 640.76) to help ensure the potency of the frozen noncellular blood components and for consistency between the labeling regulations and the regulations concerning shipping and storage temperatures of frozen noncellular blood components. As part of this rulemaking, FDA is proposing to update the temperature requirements and address as many labeling changes as possible at one time, thereby limiting the number of times establishments must revise container labels. Also, we have replaced "shall" with "must" in all places wherever it appears in the regulations.

A. Summary of Consolidation of Regulations in § 606.121

FDA is proposing to consolidate regulations so blood establishments may find all applicable labeling standards under one section of regulations. The regulations for labeling all blood and blood components would be moved from other sections of the regulations to § 606.121. The following table summarizes the regulations that would be revised, consolidated, and redesignated under the proposal. The table is intended to serve as a convenient reference for the consolidation of regulations; all revisions to the regulations are discussed later in this preamble. A current regulation listed in the table remaining unchanged may not be discussed further in the preamble.

Current Section:	Would be Revised, and/or Redesignated as:	Revisions Discussed in Section II of this document:
§ 606.121(a)	The Introductory paragraph of § 606.121, paragraph (a) is reserved	B
§ 606.121(b)	Revised only	B
§ 606.121(c)(1)	Revised only	B
§ 606.121(c)(2)	Revised only	C
§ 606.121(c)(3)	Revised only	B