

Bar Code Rule specifically invites comment on whether FDA should require the use of ISBT 128, or require "machine-readable information" as approved by the Director, CBER, or some other standard or symbology. If you are interested in commenting on the use of bar codes on container labels for blood and blood components for transfusion, please refer to the proposed Bar Code Rule and submit your comments (see 68 FR 12499).

1. Proposed revisions to § 606.121(c)(2)

FDA is proposing to amend § 606.121(c)(2) by replacing "registration number" with "unique facility identifier." This change would remove the requirement to include the FDA assigned registration number on blood and blood component labels. Although the FDA assigned registration number is acceptable as a "unique facility identifier," the proposal would also provide for the use of other recognized donation facility identification numbers, such as the ISBT facility code (which includes machine-readable information). Consistent with the general provisions for licensing in 21 CFR part 601, establishments collecting Source Plasma may use their registration number or other recognized donation facility identification number as the unique facility identifier which would aid in identifying the location where the product was collected. Under the proposal, current § 640.70(a)(10) would be removed because the requirements of § 640.70(a)(10) for "name, address, and license number" on the Source Plasma label are included in proposed § 606.121(c)(2).

2. Proposed Revisions to § 606.121(e)(1)(i)

As previously discussed in section II.B of this document, FDA is proposing to amend redesignated § 606.121(e)(1)(i) (current § 606.121(e)(1)(ii)). This revision is intended to facilitate the use of a labeling system using machine-readable information, such as ISBT 128, by providing more flexibility in labeling. Specifically, this revision would remove the labeling requirements regarding the placement and prominence of the anticoagulant.

D. Proposed Revisions Related to Temperature Requirements

FDA is proposing revisions to update temperature requirements for storage and shipment of blood and blood components. The proposed changes described in this section are intended to provide consistency with data published in Europe and to help ensure

the potency of blood and blood components by guarding against the degradation of heat labile clotting factors during storage and shipment (Ref. 1). Because these storage and shipping temperatures may be reflected in the product labeling, FDA is proposing to update the temperature requirements in this rulemaking to address as many labeling changes as possible as part of this rulemaking and enable establishments to make a number of revisions to labels for blood products at one time. This revision would simplify labeling of blood and blood components. Additionally, this approach is intended to reduce the burden on industry by minimizing the number of times blood container labels must be revised and reordered.

1. Proposed Revisions to §§ 610.53, 640.34, and 640.54

FDA is proposing to revise §§ 610.53, and 640.34(b) by changing "shall" to "must", and by changing the storage and shipping temperatures for Cryoprecipitated Antihemophilic Factor (AHF) and for Fresh Frozen Plasma to -25 °C or colder if stored for 24 months after the date of collection, and -18 to -25 °C if stored for 3 months after the date of collection. FDA is proposing changes to § 640.54 for consistency with the proposed changes in shipping and storage temperatures for Cryoprecipitated AHF.

2. Proposed Revisions to §§ 640.69, 640.70, and 640.76

As previously mentioned, FDA is proposing to redesignate current § 640.70(a)(3) as § 606.121(e)(5)(ii). FDA is proposing to revise redesignated § 606.121(e)(5)(ii) (current §§ 640.70(a)(3)), 640.69(c), and 640.76(a) and (b) by changing the storage and shipping temperatures for Source Plasma to -30 °C and -15 °C, respectively, or colder. FDA is proposing to redesignate current § 640.70(b) as § 606.121(e)(5)(v), and to revise redesignated § 606.121(e)(5)(v) by changing the storage and shipping temperatures for Source Plasma diverted for Source Plasma Salvaged to -30 °C and -15 °C, respectively, or colder.

3. Proposed Revisions to § 640.34

FDA is proposing to revise § 640.34(g)(2) to clarify that frozen plasma must be stored at appropriate temperatures to ensure product potency.

E. Proposed Changes to Clarify and Consolidate Regulations Related to Communicable Disease Testing, and Autologous Donations

The proposed revisions discussed in this section of this document would require labels for blood, blood components, and Source Plasma to include the results of the communicable disease tests performed on a sample of the donor's blood obtained at the time of the blood donation. The proposed regulations would require establishments to include on product labels the results of all communicable disease testing performed as required in § 610.40. Currently in §§ 606.121 and 640.70, only the results of tests for Hepatitis B surface antigen (HBsAg) and antibody to Human Immunodeficiency Virus (anti-HIV) are required on the label. In the **Federal Register** of June 11, 2001 (66 FR 31146), FDA published a related rulemaking entitled "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents" (the testing final rule). The proposed revisions are consistent with the requirements of the testing final rule.

1. Proposed Revisions to Redesignated § 606.121(c)(11)

FDA is proposing to redesignate current §§ 640.70(a)(8) and (a)(11) as § 606.121(c)(11) and to revise redesignated § 606.121(c)(11) to require labeling statements based on communicable disease test results. The proposed change provides that the labeling requirements apply to Source Plasma and would require establishments to label products for further manufacture with the results of all required communicable disease testing performed in accordance with § 610.40.

2. Proposed Addition to § 606.121(c)(12)

As previously described in this section, FDA is proposing to redesignate current § 606.121(c)(12) as § 606.121(c)(9), and to add new § 606.121(c)(12). Proposed § 606.121(c)(12) is intended to clarify that blood establishments would be permitted under certain circumstances to use blood or blood components which test repeatedly reactive for communicable disease agents, provided the units are appropriately labeled to indicate all test results. This labeling change is consistent with the labeling requirements of § 610.40 of the testing final rule described in the previous paragraph.