

would be redundant with redesignated § 606.121(c)(10).

#### 4. Proposed Revisions to § 606.121(d)

FDA is proposing to amend § 606.121(d) by deleting the phrase "Except for recovered plasma intended for manufacturing use or" and revise the regulation to clarify that this paragraph applies to the container labels for all blood and blood components. Additionally, § 606.121(d) is revised to remove an obsolete mail code and to provide for the use of labels printed on materials other than paper. FDA is proposing to amend § 606.121(d)(1) to clarify the labeling requirements that apply to the ABO and Rh blood grouping label. The revised regulation remains consistent with current blood establishment practice and the proposed changes are intended only to make the regulations more descriptive and precise. In addition to the conforming amendment previously discussed, proposed § 606.121(d)(2) and (d)(3) are revised to clarify the labeling requirements, as well as provide for use of a variety of labeling color schemes.

FDA is proposing to delete current § 606.121(d)(4) requiring the use of ink colors that are a visual match to the specific color samples designated by the Director, CBER, and to redesignate current § 606.121(d)(5) as § 606.121(d)(4). As proposed, redesignated § 606.121(d)(4) (current § 606.121(d)(5)) would also be revised to update the regulations consistent with current industry practice, to provide a consistent label appearance, and to facilitate the use of black and white labels produced by on-demand printers while still allowing for the use of color coded labels if blood establishments wish to continue their use. FDA believes, consistent with current industry practice, that the use of color coded labels with strict adherence to specific color samples does not increase product safety, and that the use of black and white or color coded labels without specific color samples would not have an adverse effect on identification of the ABO blood group.

#### 5. Proposed Revisions to § 606.121(e)

FDA is proposing to redesignate current § 606.121(e)(1)(i) as § 606.121(e)(1)(ii). FDA is proposing to redesignate current § 606.121(e)(1)(ii) as § 606.121(e)(1)(i) and to amend redesignated § 606.121(e)(1)(i) as discussed in section II.C.2 of this document. FDA is proposing to revise § 606.121(e)(1)(iii) by changing "shall" to "must." Section 606.121(e)(2) remains unchanged.

FDA is proposing to delete current § 606.121(e)(3) because it is redundant with proposed § 606.121(c)(4) and redesignate current § 606.121(e)(4) as § 606.121(e)(3) and current § 606.121(e)(5) as § 606.121(e)(4). Additionally, a conforming amendment is proposed to current § 606.121(j) because it refers to the current § 606.121(e)(4). FDA is proposing to update redesignated § 606.121(e)(3) (current § 606.121(e)(4)) by changing "shall" to "must."

As proposed, redesignated § 606.121(e)(4)(i) and (e)(4)(ii) (current §§ 606.121(e)(5)(i) and (e)(5)(iii), respectively) remain unchanged. Consistent with current industry practice, FDA is proposing to add § 606.121(e)(4)(iii) to require establishments to state on the container label the type of anticoagulant from which the recovered plasma was prepared.

FDA is proposing to add new § 606.121(e)(5) to include the provisions in the introductory sentence of current § 640.70(a), part of § 640.70(a)(2), and §§ 640.70(a)(3), (a)(4), (a)(7), (a)(9), and (b). Proposed § 606.121(e)(5) would clarify and consolidate in § 606.121 labeling requirements specific for Source Plasma. As proposed, redesignated § 606.121(e)(5)(i) (part of current § 640.70(a)(2)) would be updated, consistent with proposed § 606.121(c)(10), to provide flexibility in the use of upper and lowercase types in cautionary statements. Additional revisions to redesignated §§ 606.121(e)(5)(ii) (current § 640.70(a)(3)) and 606.121(e)(5)(v) (current §§ 640.70(a)(3) and (b), respectively) are discussed in section II.D of this document. FDA is proposing to redesignate current § 640.70(a)(7) as § 606.121(e)(5)(vi). Under the proposal, FDA would update redesignated § 606.121(e)(5)(vi) (current § 640.70(a)(7)) to broaden the labeling requirements to include collections from donors who are not immunized but are in specific collection programs, such as disease associated collections from donors who have antibodies to cytomegalovirus. FDA is proposing to redesignate current § 640.70(a)(4) as § 606.121(e)(5)(iii) and current § 640.70(a)(9) as § 606.121(e)(5)(iv).

#### 6. Proposed Revisions to §§ 606.121(f) and (h)

FDA is proposing to amend § 606.121(f) by revising the last sentence. The proposed change would clarify that all blood and blood components intended solely for further manufacturing, including recovered plasma and Source Plasma, do not need

to be labeled "NOT FOR TRANSFUSION" because their intended use for further manufacturing is clearly stated on the label. Section 606.121(g) remains unchanged. Under the proposal, § 606.121(h) would be revised by changing "shall" to "must", and "640.2(f)" to read "§ 610.40(g)".

#### 7. Summary of Consolidation of Regulations in § 640.70 into § 606.121

As previously discussed in this section, FDA is proposing to consolidate the existing labeling regulations in § 640.70 into § 606.121. As part of the consolidation, regulations that currently exist in both sections would be found only in § 606.121 as follows:

- § 640.70(a)(1) is deleted because it is redundant with proposed § 606.121(c)(1).
- § 640.70(a)(2) is revised and redesignated as proposed § 606.121(c)(10) and as proposed § 606.121(e)(5)(i).
- § 640.70(a)(4) is revised and redesignated as § 606.121(e)(5)(iii).
- § 640.70(a)(5) is removed because it is redundant with proposed § 606.121(c)(3).
- § 640.70(a)(6) is revised and redesignated as the second sentence of proposed § 606.121(c)(4).
- § 640.70(a)(7) is revised and redesignated as § 606.121(e)(5)(vi).
- § 640.70(a)(9) is revised and redesignated as § 606.121(e)(5)(iv).

#### *C. Proposed Revisions to Clarify and Consolidate Regulations Related to Use of a Labeling System Using Machine-Readable Information*

The proposed revisions discussed in this section of this document are primarily intended to allow for the use of a machine-readable encoded information system, such as ISBT 128. Those changes would allow manufacturers of blood, blood components, and Source Plasma to submit product specific labeling that is consistent with approved labeling formats, such as ISBT 128, to the Director, CBER, for approval without requesting a variance under § 640.120. Under this proposal, § 606.121(c)(13) would remain unchanged. In the **Federal Register** of March 14, 2003 (68 FR 12499) FDA issued a proposed rule entitled "Bar Code Label Requirements for Human Drug Products and Blood" (proposed Bar Code Rule), that 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. The proposed