

Current Section:	Would be Revised, and/or Redesignated as:	Revisions Discussed in Section II of this document:
§ 640.70(a)(7)	§ 606.121(e)(5)(vi)	B
§ 640.70(a)(8)	§ 606.121(c)(11)	E
§ 640.70(a)(9)	§ 606.121(e)(5)(iv)	B
§ 640.70(a)(10) Deleted	see § 606.121(c)(2)	C
§ 640.70(a)(11)	§ 606.121(c)(11)	E
§ 640.70(b)	§ 606.121(e)(5)(v)	D

B. Proposed Revisions to Clarify and Consolidate Regulations, Including Source Plasma Regulations

The following proposed revisions are intended to consolidate the existing labeling regulations in § 640.70 into § 606.121. As part of the consolidation, labeling regulations in § 640.70 would be moved to § 606.121, and § 640.70 would be removed from the Code of Federal Regulations (CFR). This change would enable blood establishments to find all the labeling requirements for blood and blood components, including Source Plasma, in one section of the CFR rather than having to consult different sections of the CFR when manufacturing several products. Any redundant regulations have been eliminated. FDA is proposing minor edits for clarity.

1. Proposed Revisions to § 606.121(a)

FDA is proposing to amend § 606.121(a), which describes the container label requirements for blood and blood components, by redesignating current paragraph (a) to create an introductory paragraph under § 606.121 and reserving paragraph (a). Under the proposal, the first sentence of the introductory paragraph (current § 606.121(a)) would be revised by deleting the phrase “except Source Plasma” to provide that proposed § 606.121 applies to all blood and blood components, including Source Plasma.

2. Proposed Revisions to § 606.121(b)

FDA is proposing to amend § 606.121(b) by adding the phrase “with any appropriate modifiers and attributes” to clarify that the label may be altered under specific circumstances to adequately identify the contents of a container. Examples of appropriate modifiers include “washed,” “frozen,” and “liquid.” Examples of attributes include “irradiated,” and “divided” which indicate a process change. For consistency, FDA is proposing conforming amendments to § 606.121(c)(1) and (d)(2).

3. Proposed Revisions to § 606.121(c)

Because proposed § 606.121(c)(1) applies to the container label of all blood and blood components, including Source Plasma, FDA is proposing to delete current § 640.70(a)(1). The proposed revisions to § 606.121(c)(2) are discussed in section III.C.1 of this document.

FDA is proposing to revise § 606.121(c)(3) to require that labels include all the donor numbers or a pool number that would enable establishments to trace each individual unit in the pool to the donor. Proposed § 606.121(c)(3) includes the same requirements for container labels for pooled products found in § 640.70(a)(5); therefore, FDA is proposing to delete § 640.70(a)(5).

FDA is proposing to amend § 606.121(c)(4) to clarify the expiration date of pooled plasma and to delete § 606.121(e)(3) because it would be redundant with revised § 606.121(c)(4). Under the proposal, § 640.70(a)(6) would be revised and redesignated as the second sentence of § 606.121(c)(4). If Source Plasma intended for further manufacturing into noninjectable products is pooled, the expiration date is determined from the collection date of the oldest unit in the pool, and the pooling records must show the collection date for each unit in the pool. The proposed changes would simplify the regulations by moving the requirements for determining the expiration date of Source Plasma to the section that specifies requirements for an expiration date on the container label for blood and blood components.

Current § 606.121(c)(5) is redesignated and revised, as discussed in the following paragraph. FDA is proposing that current § 606.121(c)(6) remain unchanged and be redesignated as § 606.121(c)(5). Under the proposal, current § 606.121(c)(7) remains unchanged.

FDA is proposing to simplify the wording of § 606.121(c)(8)(i). Paragraphs 606.121(c)(8)(ii) and (c)(8)(iii) remain

unchanged. FDA is proposing to redesignate § 606.121(c)(9) as § 606.121(c)(8)(iv) and to revise redesignated § 606.121(c)(8)(iv) by deleting the redundant phrase “The statement.” FDA is proposing to redesignate § 606.121(c)(5) as § 606.121(c)(8)(v) and to revise redesignated § 606.121(c)(8)(v) by deleting the redundant phrase “If the product is intended for transfusion.”

FDA is proposing to redesignate current § 606.121(c)(12) as § 606.121(c)(9). FDA is proposing to revise redesignated § 606.121(c)(9) by adding a phrase to clarify that the labeling requirements would apply to products intended for manufacturing use when an ABO and/or Rh designation is appropriate. In addition, FDA is proposing to update redesignated §§ 606.121(c)(9)(ii) and (c)(9)(iii) by using current terminology for a weak expression of the D antigen on red blood cells. The revised section would read “If the test using Anti-D Blood Grouping Reagent is negative but the test for weak D (formerly DU) is * * *

Under the proposal, current § 606.121(c)(10) is redesignated as § 606.121(c)(6).

FDA is proposing to combine current § 606.121(c)(11) and part of current § 640.70(a)(2) and redesignate the combined regulations as proposed § 606.121(c)(10). FDA is proposing to revise redesignated § 606.121(c)(10) by adding a phrase to the first sentence to clarify that blood and blood components intended for further manufacturing use, and Source Plasma are subject to these requirements. Additionally, FDA is proposing to revise redesignated § 606.121(c)(10) by adding an alternative warning statement and provide for the use of “other cautionary statements as approved by CBER.” These proposed changes and the alternative warning statement reflect current industry practice. FDA is proposing to delete current § 606.121(e)(5)(ii) because it