

3. Proposed Revisions to § 606.121(i)

FDA is proposing to revise § 606.121(i) by using more descriptive and precise terms, by replacing the word “shall” with “must” and by replacing “Whole Blood or Red Blood Cells” with “blood or blood components.” Section 606.121(i)(1) would be revised consistent with industry practice by adding “date of birth” to the list of examples of information that may be used to help ensure correct identification of the autologous transfusion recipient. In addition, FDA is proposing to delete the words “blood group” from the list of information that may identify an autologous transfusion recipient in § 606.121(i)(1). No revision is proposed for § 606.121(i)(2). FDA is proposing to revise § 606.121(i)(3) to simplify the requirements and to provide consistency with current industry practice and with the requirements for appropriate donor classification proposed in redesignated § 606.121(c)(8)(v). FDA is proposing to add new paragraph (i)(4) to clarify and update the existing requirements. Accordingly, FDA is proposing to redesignate current §§ 606.121(i)(4) and (i)(5) as § 606.121(i)(5) and (i)(6), respectively.

FDA is proposing to revise redesignated § 606.121(i)(5) (current § 606.121(i)(4)) to provide that the label for blood or blood components intended for autologous transfusion must be labeled as “FOR AUTOLOGOUS USE ONLY” if obtained from a donor who is reactive to one or more tests for evidence of infection due to communicable disease agents. Current § 606.121(i)(4) is specific for the tests currently required in the regulations. Consistent with the testing final rule, the proposed revision to redesignated § 606.121(i)(5) (current § 606.121(i)(4)) would provide for appropriate labeling regardless of how testing standards may change in the future. FDA is proposing to update redesignated § 606.121(i)(6) (current § 606.121(i)(5)), revising it by replacing “homologous” with “allogeneic.”

4. Proposed Revisions to § 606.122

FDA is proposing to amend § 606.122 *Instruction circular* by revising the introductory paragraph and paragraphs (e), (f), and (m). Section 606.122 requires that an instruction circular must be available for distribution if the product is intended for transfusion. The introductory paragraph would be revised to replace “shall” with “must”. Current § 606.122(e) requires that the instruction circular contain statements

that the product was prepared from blood that was negative when tested for antibody to human immunodeficiency virus (HIV), was nonreactive for hepatitis B surface antigen by FDA required tests and nonreactive when tested by a serological test for syphilis. Proposed § 606.122(e) would clarify that the instruction circular must contain statements regarding the results of all required infectious agent testing. By making this change, it would become unnecessary to revise the labeling regulations as testing requirements may be revised in the future. FDA is proposing to amend § 606.122(f) by updating the warning statement, which currently refers only to the hazard of transmitting hepatitis, to reflect the risk associated with the communicable disease agents for which testing is currently performed.

Note that the terms “infectious agent testing” and “communicable disease testing” (used interchangeably in this proposed rule and in guidance documents) refer to the same testing performed in accordance with § 610.40. The term “infectious agent” is used rather than “communicable disease agent” for consistency with the “Version 1.2.0 Standard.”

FDA is proposing to amend the introductory phrase in § 606.122(m), and paragraphs (m)(2), (m)(3), and (m)(5) to update the information required in the instruction circular for plasma. In the introductory sentence of § 606.122(m), FDA is proposing to update the regulations by replacing the word “shall” with “must.” Section 606.122(m)(1) would remain unchanged. FDA is proposing to revise § 606.122(m)(2) and (m)(3) to clarify that the instruction circular must contain instructions to thaw the frozen product at a temperature “appropriate for the product” and, when applicable, instructions to begin administration of the product within “a specified time” after thawing, respectively. The proposed changes would provide greater flexibility in the instruction circular, and would provide for various new thawing methods and procedures for administration that might be used in the future without requiring additional changes to the regulation.

FDA is proposing to amend § 606.122(m)(5), consistent with the changes in proposed redesignated § 606.122(e), to update the information in the instruction circular regarding the transfusion of plasma to warn of the risk of transmission of many communicable disease agents, rather than refer only to the hazard of transmitting hepatitis.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612, and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant impact of a rule on small entities.

The agency has reviewed this proposed rule and believes that it is consistent with the regulatory philosophy and principles identified in the Executive order and these two statutes. The proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. No further analysis is required under the Regulatory Flexibility Act because the agency has determined that these proposed rule amendments have no compliance costs and will not have a significant effect on a substantial number of small entities. This proposed rule also does not trigger the requirements for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in expenditure of \$100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any one year.

The purpose of the proposed rule amendments is to simplify and unify the existing labeling standards. Labeling standards are currently found in multiple sections of the regulations and these amendments would move these standards to one section of the regulations. By revising, consolidating, and redesignating these regulations, parties wishing to understand the labeling requirements will be able to