

(e) Container label requirements for particular products or groups of products.

(1) Whole Blood labels must include:

(i) The name of the applicable anticoagulant approved for use by the Director, CBER.

(ii) The volume of anticoagulant.

(iii) If tests for unexpected antibodies are positive, blood intended for transfusion must be labeled: "Contains (name of antibody)."

(2) Except for frozen, deglycerolized, or washed Red Blood Cell products, red blood cell labels must include:

(i) The volume of Whole Blood, and the type of anticoagulant with which the product was prepared.

(ii) If tests for unexpected antibodies are positive and the product is intended for transfusion, the statement: "Contains (name of antibody)."

(3) If tests for unexpected antibodies are positive, Plasma intended for transfusion must be labeled: "Contains (name of antibody)."

(4) Recovered plasma labels must include:

(i) In lieu of an expiration date, the date of collection of the oldest material in the container.

(ii) For recovered plasma not meeting the requirements for manufacture into licensable products, the statement: "Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act."

(iii) The type of anticoagulant with which the product was prepared.

(5) Source Plasma labels must include the following information:

(i) The cautionary statement, as specified in § 606.121(c)(10), must follow the proper name with any appropriate modifiers and attributes and be of similar prominence as the proper name.

(ii) The statement "Store at -30 °C or colder": Provided, That where plasma is intended for manufacturing into noninjectable products, this statement may be replaced by a statement of the temperature appropriate for manufacture of the final product to be prepared from the plasma.

(iii) The total volume or weight of plasma and total quantity and type of anticoagulant used.

(iv) When plasma collected from a donor is reactive for a serologic test for syphilis, a statement that the plasma is reactive and must be used only for the manufacturing of positive control reagents for the serologic test for syphilis.

(v) Source Plasma diverted for Source Plasma Salvaged must be relabeled "Source Plasma Salvaged" as prescribed in § 640.76 of this chapter. Immediately

following the proper name of the product, with any appropriate modifiers and attributes, the labeling must conspicuously state as applicable, "STORAGE TEMPERATURE EXCEEDED -30 °C" or "SHIPPING TEMPERATURE EXCEEDED -15 °C".

(vi) A statement as to whether the plasma was collected from nonimmunized donors, or from donors in specific collection programs approved by the Director, CBER. In the case of specific collection programs the label must state the defining characteristics of the plasma.

(f) Blood and blood components determined to be unsuitable for transfusion must be prominently labeled: "NOT FOR TRANSFUSION," and the label must state the reason the unit is considered unsuitable. The provision does not apply to blood and blood components intended solely for further manufacturing.

(g) [Reserved]

(h) The following additional information must appear on the label for blood or blood components shipped in an emergency prior to completion of required tests, in accordance with § 610.40(g) of this chapter:

(1) The statement: "FOR EMERGENCY USE ONLY BY \_\_\_\_\_."

(2) Results of any tests prescribed under §§ 610.40 and 640.5(a), (b), or (c) of this chapter completed before shipment.

(3) Indication of any tests prescribed under §§ 610.40 and 640.5(a), (b), or (c) of this chapter not completed before shipment.

(i) The following additional information must appear on the label for blood or blood components intended for autologous transfusion:

(1) Information adequately identifying the patient e.g., name, date of birth, hospital, and identification number.

(2) Date of donation.

(3) The statement: "AUTOLOGOUS DONOR."

(4) The ABO and Rh blood group and type, unless exempt under § 606.121(c)(9).

(5) In place of the allogeneic blood group label, each container of blood intended for autologous use and obtained from a donor who fails to meet any of the donor suitability requirements under § 640.3 of this chapter or who is reactive to or positive for one or more tests for evidence of infection due to communicable disease agents must be prominently and permanently labeled: "FOR AUTOLOGOUS USE ONLY."

(6) Units of blood originally intended for autologous use, except those labeled as prescribed under paragraph (i)(5) of

this section, may be issued for allogeneic transfusion provided the container label complies with all applicable provisions of paragraphs (b) through (e) of this section. In such case, the special label required under paragraphs (i)(1), (i)(2), and (i)(3) of this section must be removed or otherwise obscured.

(j) A tie-tag attached to the container may be used for providing the information required by paragraphs (e)(1)(iii), (e)(2)(ii), and (e)(3), (h), or (i)(1), (i)(2), and (i)(3) of this section.

5. Section 606.122 is amended by revising the introductory paragraph, and paragraphs (e), (f), (m)(2), (m)(3), and (m)(5) to read as follows:

#### § 606.122 Instruction circular.

An instruction circular must be available for distribution if the product is intended for transfusion. The instruction circular must provide adequate directions for use, including the following information:

\* \* \* \* \*

(e) A statement that the product was prepared from blood that was tested and found negative for evidence of infection due to the infectious agents (include the name of each infectious agent for which the blood was tested, including all FDA required tests).

(f) The statement: "Warning: The risk of communicable disease agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard."

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(m) For Plasma, the instruction circular must contain:

(1) \* \* \*

(2) Instructions to thaw the frozen product at a temperature appropriate for the product.

(3) When applicable, instructions to begin administration of the product within a specified time after thawing.

(4) \* \* \*

(5) A statement that this product has the same risk of transmitting communicable disease agents as Whole Blood; other plasma volume expanders without this risk are available for treating hypovolemia.

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#### PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

6. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

7. Section 610.53 is amended by revising paragraph (c) in the table for