§ 606.121 Container label.

(a) The container label requirements are designed to facilitate the use of a uniform container label for blood and blood components intended for use in transfusion or further manufacture by all blood establishments.

(b) The label provided by the collecting facility and the initial processing facility must not be removed, altered, or obscured, except that the label may be altered to indicate the proper name of the product, with any appropriate modifiers and attributes, and other information required to identify accurately the contents of a container after blood components considered finished products have been prepared.

(c) The container label must include the following information, as well as other specialized information as required in this section for specific products:

(1) The proper name of the product in a prominent position, with any appropriate modifiers and attributes.

(2) The name, address, unique facility identifier, and, if a licensed product, the license number of each manufacturer; except the container label for blood and blood components for further manufacture is not required to include a unique facility identifier.

(3) The donor or lot number relating the unit to the donor. If pooled, all donor numbers, all donation numbers, or a pool number that is traceable to each individual unit comprising the pool.

(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.

(ii) If Source Plasma intended for manufacture, process, repack, or relabel by another manufacture by all blood establishments intended for use in transfusion or further manufacture, a statement listing the negative results of serological syphilis testing under §§610.40(i) and 640.65(b) of this chapter.

(iii) If the donation is tested and found negative; except that the container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research (CBER). (C) Benefits, such as time off from work, membership in blood assurance programs, and cancellation of nonreplacement fees that are not readily convertible to cash, do not constitute monetary payment within the meaning of this paragraph.

(b) The label provided by the collecting facility and the initial processing facility must not be removed, altered, or obscured, except that the label may be altered to indicate the proper name of the product, with any appropriate modifiers and attributes, and other information required to identify accurately the contents of a container after blood components considered finished products have been prepared.

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(1) The proper name of the product in a prominent position, with any appropriate modifiers and attributes.

(2) The name, address, unique facility identifier, and, if a licensed product, the license number of each manufacturer; except the container label for blood and blood components for further manufacture is not required to include a unique facility identifier.

(3) The donor or lot number relating the unit to the donor. If pooled, all donor numbers, all donation numbers, or a pool number that is traceable to each individual unit comprising the pool.

(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.

(ii) If Source Plasma intended for manufacture, process, repack, or relabel by another manufacture by all blood establishments intended for use in transfusion or further manufacture, a statement listing the negative results of serological syphilis testing under §§610.40(i) and 640.65(b) of this chapter.

(iii) If the donation is tested and found negative; except that the container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, CBER.

(d) The label provided by the collecting facility and the initial processing facility must not be removed, altered, or obscured, except that the label may be altered to indicate the proper name of the product, with any appropriate modifiers and attributes, and other information required to identify accurately the contents of a container after blood components considered finished products have been prepared.

(e) The container label must include the following information, as well as other specialized information as required in this section for specific products:

(1) The proper name of the product in a prominent position, with any appropriate modifiers and attributes.

(2) The name, address, unique facility identifier, and, if a licensed product, the license number of each manufacturer; except the container label for blood and blood components for further manufacture is not required to include a unique facility identifier.

(3) The donor or lot number relating the unit to the donor. If pooled, all donor numbers, all donation numbers, or a pool number that is traceable to each individual unit comprising the pool.

(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.

(ii) If Source Plasma intended for manufacture, process, repack, or relabel by another manufacture by all blood establishments intended for use in transfusion or further manufacture, a statement listing the negative results of serological syphilis testing under §§610.40(i) and 640.65(b) of this chapter.

(iii) If the donation is tested and found negative; except that the container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, CBER.

(d) The label provided by the collecting facility and the initial processing facility must not be removed, altered, or obscured, except that the label may be altered to indicate the proper name of the product, with any appropriate modifiers and attributes, and other information required to identify accurately the contents of a container after blood components considered finished products have been prepared.

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(1) The proper name of the product in a prominent position, with any appropriate modifiers and attributes.

(2) The name, address, unique facility identifier, and, if a licensed product, the license number of each manufacturer; except the container label for blood and blood components for further manufacture is not required to include a unique facility identifier.

(3) The donor or lot number relating the unit to the donor. If pooled, all donor numbers, all donation numbers, or a pool number that is traceable to each individual unit comprising the pool.

(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.

(ii) If Source Plasma intended for manufacture, process, repack, or relabel by another manufacture by all blood establishments intended for use in transfusion or further manufacture, a statement listing the negative results of serological syphilis testing under §§610.40(i) and 640.65(b) of this chapter.

(iii) If the donation is tested and found negative; except that the container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, CBER.

(d) The label provided by the collecting facility and the initial processing facility must not be removed, altered, or obscured, except that the label may be altered to indicate the proper name of the product, with any appropriate modifiers and attributes, and other information required to identify accurately the contents of a container after blood components considered finished products have been prepared.

(e) The container label must include the following information, as well as other specialized information as required in this section for specific products:

(1) The proper name of the product in a prominent position, with any appropriate modifiers and attributes.

(2) The name, address, unique facility identifier, and, if a licensed product, the license number of each manufacturer; except the container label for blood and blood components for further manufacture is not required to include a unique facility identifier.

(3) The donor or lot number relating the unit to the donor. If pooled, all donor numbers, all donation numbers, or a pool number that is traceable to each individual unit comprising the pool.

(4)(i) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration.

(ii) If Source Plasma intended for manufacture, process, repack, or relabel by another manufacture by all blood establishments intended for use in transfusion or further manufacture, a statement listing the negative results of serological syphilis testing under §§610.40(i) and 640.65(b) of this chapter.

(iii) If the donation is tested and found negative; except that the container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, CBER.
transfusion and regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(ii) What blood products are subject to this machine-readable requirement? All blood and blood components intended for transfusion are subject to the machine-readable information label requirement in this section.

(iii) How must the information appear? The machine-readable information must:

(A) Be unique to the blood or blood component;

(B) Be surrounded by sufficient blank space so that the machine-readable information can be scanned correctly; and

(C) Remain intact under normal conditions of use.

(iv) Where does the machine-readable information go? The machine-readable information must appear on the label of any blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient.

(v) Except for frozen, deglycerolized, or washed Red Blood Cell products, Red Blood Cell labels must include:

(A) The type of anticoagulant, and if applicable, the volume of Whole Blood and type of additive solution, with which the product was prepared.

(B) The statement “Contains (name of antibody).”

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

(1) Whole Blood labels must include:

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

(B) The volume of anticoagulant.

(2) Recovered plasma labels must include:

(A) The cautionary statement, as specified in paragraph (c)(10) of this section, must follow the proper name with any appropriate modifiers and attributes and be of similar prominence as the proper name.

(B) The statement “Store at -20 °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.

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

(D) The proper name of the product, with any appropriate modifiers and attributes, the donor classification statement, and the statement “properly identify intended recipient” may be printed in solid red or in solid black.

(E) The following color scheme may be used for differentiating ABO Blood groups:

<table>
<thead>
<tr>
<th>Blood group</th>
<th>Color of label</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>Blue</td>
</tr>
<tr>
<td>A</td>
<td>Yellow</td>
</tr>
<tr>
<td>B</td>
<td>Pink</td>
</tr>
<tr>
<td>AB</td>
<td>White</td>
</tr>
</tbody>
</table>

(4) Special labels, such as those described in paragraphs (h) and (i) of this section, may be color-coded.
§ 606.122 Instruction circular.

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

(a) Instructions to mix the product before use.

(b) Instructions to use a filter in the administration equipment.

(c) The statement “Do Not Add Medications” or an explanation concerning allowable additives.

(d) A description of the product, its source, and preparation, including the name and proportion of the anticoagulant used in collecting the Whole Blood from each product is prepared.

(e) Statements that the product was prepared from blood that was negative when tested for antibody to Human Immunodeficiency Virus (HIV) and nonreactive for hepatitis B surface antigen by FDA required tests and nonreactive when tested for syphilis by a serologic test for syphilis (STS).

(f) The statements: “Warning. The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard.”

(g) The names of cryoprotective agents and other additives that may still be present in the product.

(h) The names and results of all tests performed when necessary for safe and effective use.

(i) The use of the product, indications, contraindications, side effects and hazards, dosage and administration recommendations.

(j) [Reserved]

(k) For Red Blood Cells, the instruction circular shall contain:

(1) Instructions to administer a suitable plasma volume expander if Red Blood Cells are substituted when Whole Blood is the indicated product.