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product is to be exported provided that in all such cases the minimum label requirements prescribed in § 610.60 are observed.

§ 610.67 Bar code label requirements.

Biological products must comply with the bar code requirements at § 201.25 of this chapter. However, the bar code requirements do not apply to devices regulated by the Center for Biologics Evaluation and Research or to blood and blood components intended for transfusion. For blood and blood components intended for transfusion, the requirements at § 606.121(c)(13) of this chapter apply instead.

[69 FR 9171, Feb. 26, 2004]

§ 610.68 Exceptions or alternatives to labeling requirements for biological products held by the Strategic National Stockpile.

(a) The appropriate FDA Center Director may grant an exception or alternative to any provision listed in paragraph (f) of this section and not explicitly required by statute, for specified lots, batches, or other units of a biological product, if the Center Director determines that compliance with such labeling requirement could adversely affect the safety, effectiveness, or availability of such product that is or will be included in the Strategic National Stockpile.

(b)(1)(i) A Strategic National Stockpile official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores a biological product that is or will be included in the Strategic National Stockpile may submit, with written concurrence from a Strategic National Stockpile official, a written request for an exception or alternative described in paragraph (a) of this section to the Center Director.

(ii) The Center Director may grant an exception or alternative described in paragraph (a) of this section on his or her own initiative.

(2) A written request for an exception or alternative described in paragraph (a) of this section must:

(i) Identify the specified lots, batches, or other units of the biological product that would be subject to the exception or alternative;

(ii) Identify the labeling provision(s) listed in paragraph (f) of this section that are the subject of the exception or alternative request;

(iii) Explain why compliance with such labeling provision(s) could adversely affect the safety, effectiveness, or availability of the specified lots, batches, or other units of the biological product that are or will be included in the Strategic National Stockpile;

(iv) Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product, given the anticipated circumstances of use of the product;

(v) Provide a draft of the proposed labeling of the specified lots, batches, or other units of the biological product subject to the exception or alternative; and

(vi) Provide any other information requested by the Center Director in support of the request.

(c) The Center Director must respond in writing to all requests under this section.

(d) A grant of an exception or alternative under this section will include any safeguards or conditions deemed appropriate by the Center Director so that the labeling of product subject to the exception or alternative includes the information necessary for the safe and effective use of the product, given the anticipated circumstances of use.

(e) If you are a sponsor receiving a grant of a request for an exception or alternative to the labeling requirements under this section:

(1) You need not submit a supplement under § 601.12(f)(1) through (f)(2) of this chapter; however,

(2) You must report any grant of a request for an exception or alternative under this section as part of your annual report under § 601.12(f)(3) of this chapter.

(f) The Center Director may grant an exception or alternative under this section to the following provisions of this chapter, to the extent that the requirements in these provisions are not explicitly required by statute:

(1) § 610.60;

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(2) § 610.61(c) and (e) through (r);
(3) § 610.62;
(4) § 610.63;
(5) § 610.64;
(6) § 610.65; and
(7) § 312.6.

[72 FR 73600, Dec. 28, 2007]

PART 630—REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

Subpart A—General Provisions

Subpart B—Donor Eligibility Requirements

Subpart C—Donor Notification

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371; 42 U.S.C. 216, 262, 264.

SOURCE: 66 FR 31176, June 11, 2001, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 80 FR 29898, May 22, 2015, unless otherwise noted.

§ 630.1 Purpose and scope.

(a) *What is the purpose of subparts A, B, and C of this part*? The purpose of these subparts, together with §§ 610.40 and 610.41 of this chapter, is to provide certain minimum criteria for each donation of blood and blood components, for:

(1) Determining the eligibility of a donor of blood and blood components;

(2) Determining the suitability of the donation of blood and blood components; and

(3) Notifying a donor who is deferred from donation.

(b) *Who must comply with subparts A, B, and C of this part*? Blood establishments that manufacture blood and blood components, as defined in § 630.3(a) and (b), must comply with subparts A, B, and C of this part.

§ 630.3 Definitions.

As used in this part and in part 610, subpart E, and part 640 of this chapter:

(a) *Blood* means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.

(b) *Blood component* means a product containing a part of blood separated by physical or mechanical means.

(c) *Donor* means a person who: (1) Donates blood or blood components for transfusion or for further manufacturing use; or

(2) Presents as a potential candidate for such donation.

(d) *Eligibility of a donor* means the determination that the donor is qualified to donate blood and blood components.

(e) *Infrequent plasma donor* means a donor who has:

(1) Not donated plasma by plasmapheresis or a co-collection of plasma with another blood component in the preceding 4 weeks; and

(2) Not donated more than 12.0 liters of plasma (14.4 liters of plasma for donors weighing more than 175 pounds) in the past year.

(f) *Intimate contact with risk for a relevant transfusion-transmitted infection* means having engaged in an activity that could result in the transfer of potentially infectious body fluids from one person to another.

(g) *Physician substitute* means a trained and qualified person(s) who is:

(1) A graduate of an education program for health care workers that includes clinical training;

(2) Currently licensed or certified as a health care worker in the jurisdiction where the collection establishment is located;

(3) Currently certified in cardiopulmonary resuscitation; and

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