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 §610.12(f)(1) through (f)(2) of this chapter; however,

(2) §610.61(c) and (e) through (r);

(3) §610.62;

(4) §610.63;

(5) §610.64;

(6) §610.65; and

(7) §312.6.

PART 630—GENERAL REQUIREMENTS FOR BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES


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

§630.6 Donor notification.

(a) Notification of donors. You, an establishment that collects blood or blood components, must make reasonable attempts to notify any donor, including an autologous donor, who has been deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as required by §610.41 of this chapter; or who has been determined not to be suitable as a donor based on suitability criteria under §640.3 or §640.63 of this chapter. You must attempt to obtain the results of supplemental testing required under §610.40(e) of this chapter prior to notifying a donor of the deferral. If notification occurs prior to receipt of such results, you must also notify a deferred donor of the results of the supplemental testing. You must notify a donor as described in paragraph (b) of this section.

(b) Content of notification. You must provide the following information to a donor deferred or determined not to be suitable as a donor as described in paragraph (a) of this section:

(1) That the donor is deferred or determined not to be suitable for donation and the reason for that decision;

(2) Where appropriate, the types of donation of blood or blood components that the donor should not donate in the future;

(3) Where applicable, the results of tests for evidence of infection due to communicable disease agent(s) that were a basis for deferral under §610.41 of this chapter, including results of
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supplemental (i.e., additional, more specific) tests as required in §610.40(e) of this chapter; and,

(4) Where appropriate, information concerning medical followup and counseling.

(c) Time period for notification. You must make reasonable attempts to notify the donor within 8 weeks after determining that the donor is deferred or determined not to be suitable for donation as described in paragraph (a) of this section. You must document that you have successfully notified the donor or when you are unsuccessful that you have made reasonable attempts to notify the donor.

(d) Autologous donors. (1) You also must provide the following information to the referring physician of an autologous donor who is deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as described in paragraph (a) of this section:

(i) Information that the autologous donor is deferred based on the results of tests for evidence of infection due to communicable disease agent(s), as required under §610.41 of this chapter, and the reason for that decision;

(ii) Where appropriate, the types of donation of blood or blood components that the autologous donor should not donate in the future; and

(iii) The results of tests for evidence of infection due to communicable disease agent(s), that were a basis for deferral under §610.41 of this chapter, including results of supplemental (i.e., additional, more specific) tests as required in §610.40(e) of this chapter.

(2) You must make reasonable attempts to notify the autologous donor’s referring physician within 8 weeks after determining that the autologous donor is deferred as described in paragraph (a) of this section. You must document that you have successfully notified the autologous donor’s referring physician or when you are unsuccessful that you have made reasonable attempts to notify the physician.