weeks after receiving the results of further testing for evidence of HCV infection from the collecting establishment, or after receiving the donor's reactive screening test result for HCV if further testing is not available, or if under an IND or IDE, is exempted for such use by FDA.

(c) Actions under this section do not constitute a recall as defined in §7.3 of this chapter.

[72 FR 48799, Aug. 24, 2007, as amended at 80 FR 29897, May 22, 2015]

§ 610.48 [Reserved]

Subpart F—Dating Period Limitations

§ 610.50 Date of manufacture for biological products.

(a) *When the dating period begins.* The dating period for a product must begin on the date of manufacture as described in paragraphs (b) and (c) of this section. The dating period for a combination of two or more products must be no longer than the dating period of the component with the shortest dating period.

(b) *Determining the date of manufacture for biological products other than Whole Blood and blood components.* The date of manufacture for biological products, other than Whole Blood and blood components, must be identified in the approved biologics license application as one of the following, whichever is applicable: The date of:

(1) Potency test or other specific test as described in a biologics license application or supplement to the application;

(2) Removal from animals or humans;

(3) Extraction;

(4) Solution;

(5) Cessation of growth;

(6) Final sterile filtration of a bulk solution;

(7) Manufacture as described in part 660 of this chapter; or

(8) Other specific manufacturing activity described in a biologics license application or supplement to the biologics license application.

(c) *Determining the date of manufacture for Whole Blood and blood components.* (1) The date of manufacture for Whole Blood and blood components must be one of the following, whichever is applicable:

(i) Collection date and/or time;

(ii) Irradiation date;

(iii) The time the red blood cell product was removed from frozen storage for deglycerolization;

(iv) The time the additive or rejuvenation solution was added;

(v) The time the product was entered for washing or removing plasma (if prepared in an open system);

(vi) As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA; or

(vii) As approved by the Director, Center for Biologics Evaluation and Research, in a biologics license application or supplement to the application.

(2) For licensed Whole Blood and blood components, the date of manufacture must be identified in the approved biologics license application or supplement to the application.

[81 FR 26691, May 4, 2016]

§ 610.53 Dating periods for Whole Blood and blood components.

(a) *General.* Dating periods for Whole Blood and blood components are specified in the table in paragraph (b) of this section.

(b) *Table of dating periods.* In using the table in this paragraph, when a product in column A is stored at the storage temperature prescribed in column B, storage of a product must not exceed the dating period specified in column C, unless a different dating period is specified in the instructions for use by the blood collection, processing and storage system approved or cleared for such use by FDA. Container labels for each product must include the recommended storage temperatures.

WHOLE BLOOD AND BLOOD COMPONENTS STORAGE TEMPERATURES AND DATING PERIODS

A	B	C
Product	Storage temperature	Dating period
Whole Blood		
ACD, CPD, CP2D	Between 1 and 6 °C	21 days from date of collection.
CPDA–1	do[1]	35 days from date of collection.
Red Blood Cells		
ACD, CPD, CP2D	Between 1 and 6 °C	21 days from date of collection.
CPDA–1	do	35 days from date of collection.
Additive solutions	do	42 days from date of collection.
Open system (e.g., deglycerolized, washed)	do	24 hours after entering bag.
Deglycerolized in closed system with additive solution added.	do	14 days after entering bag.
Irradiated	do	28 days from date of irradiation or original dating, whichever is shorter.
Frozen	−65 °C or colder	10 years from date of collection.
Platelets		
Platelets	Between 20 and 24 °C	5 days from date of collection.
Platelets	Other temperatures according to storage bag instructions.	As specified in the instructions for use by the blood collection, processing and storage system approved or cleared for such use by FDA.
Plasma		
Fresh Frozen Plasma	−18 °C or colder	1 year from date of collection.
Plasma Frozen Within 24 Hours After Phlebotomy.	do	1 year from date of collection.
Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up To 24 Hours After Phlebotomy.	do	1 year from date of collection.
Plasma Cryoprecipitate Reduced	do	1 year from date of collection.
Plasma	do	5 years from date of collection.
Liquid Plasma	Between 1 and 6 °C	5 days from end of Whole Blood dating period.
Source Plasma (frozen injectable)	−20 °C or colder	10 years from date of collection.
Source Plasma Liquid (injectable)	10 °C or colder	According to approved biologics license application.
Source Plasma (noninjectable)	Temperature appropriate for final product.	10 years from date of collection.
Therapeutic Exchange Plasma	−20 °C or colder	10 years from date of collection.
Cryoprecipitated AHF		
Cryoprecipitated AHF	−18 °C or colder	1 year from date of collection of source blood or from date of collection of oldest source blood in pre-storage pool.
Source Leukocytes		
Source Leukocytes	Temperature appropriate for final product.	In lieu of expiration date, the collection date must appear on the label.

[1] The abbreviation ''do.'' for ditto is used in the table to indicate that the previous line is being repeated.

[81 FR 26691, May 4, 2016]

Subpart G—Labeling Standards

§ 610.60 Container label.

(a) *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:

(1) The proper name of the product;

(2) The name, address, and license number of manufacturer;

(3) The lot number or other lot identification;

(4) The expiration date;