

Cryoprecipitated AHF, and Plasma products for the item Fresh Frozen Plasma to read as follows:

§ 610.53 Dating periods for licensed biological products.

(c) * * *

* * * * *

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
* * * * *			
Cryoprecipitated AHF	do	do	24 months from the date of collection of source blood providing labeling recommends storage at -25 °C or colder or 3 months from the date of collection of source blood providing labeling recommends storage between -18 to -25 °C.
* * * * *			
Plasma products 1. Fresh Frozen Plasma	Not applicable	do	24 months from the date of collection of source blood providing labeling recommends storage at -25 °C or colder or 3 months from the date of collection of source blood providing labeling recommends storage between -18 to -25 °C.

* * * * *

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

8. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

9. Section 640.34 is amended by revising paragraphs (b) and (g)(2) to read as follows:

§ 640.34 Processing.

(a) * * *

(b) *Fresh Frozen Plasma.* Fresh Frozen Plasma must be prepared from blood collected by uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma must be separated from the red blood cells, and placed in a freezer within 8 hours or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. The plasma must be stored at -25 °C or colder if the expiration is 24 months; and at -18 to -25 °C if the expiration is 3 months.

* * * * *

(g) * * *

(2) With the exception of Platelet Rich Plasma and Liquid Plasma the final product must be inspected for evidence of thawing or breakage at the time of

issuance. The containers need not be stored in a manner that shows evidence of thawing if records of continuous monitoring can establish that the appropriate storage temperature recommended on the labeling for the product was maintained throughout the storage period. If continuous monitoring of the product is not available, the final product must be stored in a manner that will show evidence of thawing and must not be issued if there is any evidence of thawing.

* * * * *

10. Section 640.54 is amended by revising paragraph (a)(3) to read as follows:

§ 640.54 Processing.

(a) * * *

(3) Immediately after separation and freezing of the plasma, the plasma must be stored and maintained at the appropriate storage temperature recommended on the labeling for the product until thawing of the plasma for further processing to remove the Cryoprecipitated AHF.

* * * * *

11. Section 640.69 is amended by revising paragraph (c) to read as follows:

§ 640.69 General requirements.

* * * * *

(c) *Inspection.* Source Plasma intended for further manufacturing into injectable products must be inspected for evidence of thawing at the time of

issuance, except that inspection of individual plasma containers need not be made if the records of continuous monitoring of the storage temperature establish that the temperature remained at -30 °C or colder. If there is evidence that the storage temperature has not been maintained at -30 °C or colder, the plasma may be relabeled and issued as provided in § 640.76(a) of this chapter.

* * * * *

§ 640.70 [Removed]

12. Section 640.70 *Labeling* is removed.

§ 640.76 [Amended]

13. Section 640.76 *Products stored or shipped at unacceptable temperatures* is amended as follows:

a. In paragraphs (a)(1) and (a)(2) by removing “-20 °C” and adding in its place “-30 °C” wherever it appears;

b. In paragraphs (a)(1), (a)(2), and (b) by removing “shall” and adding in its place “must” wherever it appears;

c. In paragraphs (a)(2) and (b) by removing “-5 °C” and adding in its place “-15 °C” wherever it appears.

Dated: July 12, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-19289 Filed 7-29-03; 8:45 am]

BILLING CODE 4160-01-S