identified by number or other symbol so as to relate it to the donor of that unit of red cells.

[38 FR 32089, Nov. 20, 1973, as amended at 43 FR 34460, Aug. 4, 1978; 50 FR 4139, Jan. 29, 1985; 64 FR 45372, Aug. 19, 1999; 66 FR 1836, Jan. 10, 2001; 66 FR 40890, Aug. 6, 2001]

§ 640.17 Modifications for specific products.

Red Blood Cells Frozen: A cryophylactic substance may be added to the Red Blood Cells for extended manufacturers' storage at −65 °C or colder, provided the manufacturer submits data considered by the Director, Center for Biologics Evaluation and Research, as adequately demonstrating through in vivo cell survival and other appropriate tests that the addition of the substance, the materials used and the processing methods results in a final product that meets the required standards of safety, purity, and potency for Red Blood Cells, and that the frozen product will maintain those properties for the prescribed dating period. Section 640.11 (a) and (b) do not apply while a cryophylactic substance is present.

[38 FR 32089, Nov. 20, 1973, as amended at 41 FR 18292, May 3, 1976; 49 FR 23834, June 8, 1984; 50 FR 4139, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990; 63 FR 16685, Apr. 6, 1998]

Subpart C—Platelets

§ 640.20 Platelets.

(a) *Proper name and definition.* The proper name of this product shall be Platelets. The product is defined as platelets collected from one unit of blood and resuspended in an appropriate volume of original plasma, as prescribed in § 640.24(d).

(b) *Source.* The source material for Platelets is plasma which may be obtained by whole blood collection or by plateletpheresis.

[40 FR 4304, Jan. 29, 1975, as amended at 47 FR 49021, Oct. 29, 1982; 50 FR 4139, Jan. 29, 1985; 72 FR 45887, Aug. 16, 2007]

§ 640.21 Eligibility of donors.

(a) Establishments must determine the eligibility of donors of platelets derived from Whole Blood and donors of platelets collected by plateletpheresis in accordance with §§ 630.10 and 630.15 of this chapter, except as provided in this section.

(b) A plateletpheresis donor must not serve as the source of platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function.

(c) A Whole Blood donor must not serve as the source of platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function unless the unit is labeled to identify the ingested drug that adversely affects platelet function.

(d) If you are collecting platelets by plateletpheresis, you must assess and monitor the donor's platelet count.

(1) You must take adequate and appropriate steps to assure that the donor's platelet count is at least 150,000 platelets per microliter (/μL) before plateletpheresis begins. Exception: If you do not have records of a donor's platelet count from prior donations and you are not able to assess the donor's platelet count either prior to or immediately following the initiation of the collection procedure, you may collect platelets by plateletpheresis, but you must not collect 9.0×10^{11} or more platelets from that donor.

(2) You must defer from platelet donation a donor whose pre-donation platelet count is less than 150,000 platelets/μL until a subsequent pre-donation platelet count indicates that the donor's platelet count is at least 150,000 platelets/μL; and

(3) You must take appropriate steps to assure that the donor's intended post-donation platelet count will be no less than 100,000 platelets/μL.

(e) *Frequency of plateletpheresis collection.* (1) The donor may donate no more than a total of 24 plateletpheresis collections during a 12-month rolling period.

(2) When you collect fewer than 6×10^{11} platelets, you must wait at least 2 calendar days before any subsequent plateletpheresis collection. You must not attempt to collect more than 2 collections within a 7 calendar day period.

(3) When you collect 6×10^{11} or more platelets, you must wait at least 7 calendar days before any subsequent plateletpheresis collection.

(4) *Exception.* For a period not to exceed 30 calendar days, a donor may serve as a dedicated plateletpheresis donor for a single recipient, in accordance with § 610.40(c)(1) of this chapter, as often as is medically necessary, provided that the donor is in good health, as determined and documented by the responsible physician, and the donor's platelet count is at least 150,000 platelets/μL, measured at the conclusion of the previous donation or before initiating plateletpheresis for the current donation.

(f) *Deferral of plateletpheresis donors due to red blood cell loss.* (1) You must defer a donor from donating platelets by plateletpheresis or a co-collection of platelets and plasma by apheresis for 8 weeks if the donor has donated a unit of Whole Blood, or a single unit of Red Blood Cells by apheresis unless at least 2 calendar days have passed and the extracorporeal volume of the apheresis device is less than 100 milliliters.

(2) You must defer a donor from donating platelets for a period of 16 weeks if the donor donates two units of Red Blood Cells during a single apheresis procedure.

(3) You must defer a donor for 8 weeks or more if the cumulative red blood cell loss in any 8 week period could adversely affect donor health.

(g) The responsible physician must obtain the informed consent of a plateletpheresis donor on the first day of donation, and at subsequent intervals no longer than 1 year.

(1) The responsible physician must explain the risks and hazards of the procedure to the donor; and

(2) The explanation must be made in such a manner that the donor may give consent, and has a clear opportunity to refuse the procedure.

[80 FR 29904, May 22, 2015]

§ 640.22 Collection of source material.

(a) Whole blood used as the source of Platelets shall be collected as prescribed in § 640.4.

(b) [Reserved]

(c) If plateletpheresis is used, the procedure for collection must be as prescribed in §§ 640.21, 640.64 (except paragraph (c)), and 640.65, or as described in an approved biologics license application (BLA) or an approved supplement to a BLA.

(d) The phlebotomy shall be performed by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor's tissue.

[40 FR 4304, Jan. 29, 1975, as amended at 45 FR 27927, Apr. 25, 1980; 49 FR 23834, June 8, 1984; 50 FR 4139, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990; 59 FR 49351, Sept. 28, 1994; 64 FR 45372, Aug. 19, 1999; 64 FR 56453, Oct. 20, 1999; 72 FR 45887, Aug. 16, 2007; 80 FR 29904, May 22, 2015]

§ 640.23 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Platelets shall be tested as prescribed in § 610.40 of this chapter and § 640.5 (b) and (c).

(b) The tests shall be performed on a sample of blood collected at the time of collecting the source blood, and such sample container shall be labeled with the donor's number before the container is filled.

[40 FR 4304, Jan. 29, 1975, as amended at 50 FR 4139, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988; 64 FR 45372, Aug. 19, 1999; 66 FR 1836, Jan. 10, 2001; 66 FR 31165, June 11, 2001; 80 FR 29904, May 22, 2015]

§ 640.24 Processing.

(a) Separation of plasma and platelets and resuspension of the platelets must be in a closed system. Platelets must not be pooled during processing unless the platelets are pooled as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research.

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 and 24 °C unless it must be transported from the collection center to the processing laboratory. During such transport, all reasonable methods shall be used to maintain the temperature as close as possible to a range between 20 and 24 °C until it arrives at the processing laboratory where it shall be held between 20 and 24 °C until the platelets are separated. The platelet concentrate shall be separated within 4 hours or within the timeframe specified in the directions