PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood

Sec.
640.1 Whole Blood.
640.2 General requirements.
640.3 Suitability of donor.
640.4 Collection of the blood.
640.5 Testing the blood.
640.6 Modifications of Whole Blood.

Subpart B—Red Blood Cells

640.10 Red Blood Cells.
640.11 General requirements.
640.12 Suitability of donor.
640.13 Collection of the blood.
640.14 Testing the blood.
640.15 Segments for testing.
640.16 Processing.
640.17 Modifications for specific products.

Subpart C—Platelets

640.20 Platelets.
640.21 Suitability of donors.
640.22 Collection of source material.
640.23 Testing the blood.
640.24 Processing.
640.25 General requirements.
640.27 Emergency provisions.

Subpart D—Plasma

640.30 Plasma.
640.31 Suitability of donors.
640.32 Collection of source material.
640.33 Testing the blood.
640.34 Processing.

Subpart E [Reserved]

Subpart F—Cryoprecipitate

640.50 Cryoprecipitate AHF.
640.51 Suitability of donors.
640.52 Collection of source material.
640.53 Testing the blood.
640.54 Processing.
640.56 Quality control test for potency.

Subpart G—Source Plasma

640.60 Source Plasma.
640.61 Informed consent.
640.62 Medical supervision.
640.63 Suitability of donor.
640.64 Collection of blood for Source Plasma.
640.65 Plasmapheresis.
640.66 Immunization of donors.
640.67 Laboratory tests.
640.68 Processing.

Subpart H—Albumin (Human)

640.80 Albumin (Human).
640.81 Processing.
640.82 Tests on final product.
640.83 General requirements.
640.84 Labeling.

Subpart I—Plasma Protein Fraction (Human)

640.90 Plasma Protein Fraction (Human).
640.91 Processing.
640.92 Tests on final product.
640.93 General requirements.
640.94 Labeling.

Subpart J—Immune Globulin (Human)

640.100 Immune Globulin (Human).
640.101 General requirements.
640.102 Manufacture of Immune Globulin (Human).
640.103 The final product.
640.104 Potency.

Subpart K [Reserved]

Subpart L—Alternative Procedures

640.120 Alternative procedures.


SOURCE: 38 FR 32089, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21-12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—Whole Blood

§ 640.1 Whole Blood.

The proper name of this product shall be Whole Blood. Whole Blood is defined as blood collected from human donors for transfusion to human recipients.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4138, Jan. 29, 1985]