Subpart F—Cryoprecipitate

§ 640.50 Cryoprecipitated AHF.
(a) Proper name and definition. The proper name of this product shall be Cryoprecipitated AHF. The product is defined as a preparation of antihemophilic factor, which is obtained from a single unit of plasma collected and processed in a closed system.
(b) Source. The source material for Cryoprecipitated AHF shall be plasma which may be obtained by whole blood collection or by plasmapheresis.

§ 640.51 Suitability of donors.
(a) Whole blood donors shall meet the criteria for suitability prescribed in §640.3.
(b) Plasmapheresis donors shall meet the criteria for suitability prescribed in §640.63, excluding the phrase “other than malaria” in paragraph (c)(9) of that section. Informed consent shall be required as prescribed in §640.61.

§ 640.52 Collection of source material.
(a) Whole blood used as a source of Cryoprecipitated AHF shall be collected as prescribed in §640.4. Whole blood from which both Platelets and Cryoprecipitated AHF is derived shall be maintained as required under §640.24 until the platelets are removed.
(b) If plasmapheresis is used, the procedure for collection shall be as prescribed in §§640.62, 640.64 (except that paragraph (c)(3) of that section shall not apply), and 640.65.

§ 640.53 Testing the blood.
(a) Blood from which plasma is separated for the preparation of Cryoprecipitated AHF shall be tested as prescribed in §610.40 of this chapter and §640.5 (a), (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.
(c) Manufacturers of Cryoprecipitated AHF obtained from plasma collected by plasmapheresis shall have testing and record-keeping responsibilities equivalent to those prescribed in §§640.71 and 640.72.