§ 640.15 Segments for testing.

Segments collected in integral tubing shall meet the following standards:

(a) One or more segments shall be provided with each unit of Whole Blood or Red Blood Cells when issued or reissued.

(b) Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

§ 640.16 Processing.

(a) Separation. Within the timeframe specified in the directions for use for the blood collecting, processing, and storage system used, Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation. A portion of the plasma sufficient to insure optimal cell preservation shall be left with the red cells except when a cryoprotective substance or additive solution is added for prolonged storage.

(b) Sterile system. All surfaces that come in contact with the red cells shall be sterile and pyrogen-free.

(c) Final containers. Final containers used for Red Blood Cells shall be sterile or pyrogen-free.

§ 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(c). At the time of filling, if a different container is used, it shall be marked or identified by number or other symbol so as to relate it to the donor of that unit of red cells.

Subpart C—Platelets

§ 640.21 Suitability of donors.

(a) Whole blood donors shall meet the criteria for suitability prescribed in §640.3.

(b) [Reserved]

(c) Plateletapheresis donors must meet the criteria for suitability as prescribed in §§640.3 and 640.63(c)(6) or as described in an approved biologics license application (BLA) or an approved