ure of each filling, including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(ii) A total of no less than two 25-milliliter volumes, in a frozen state (−60° C), of preclarification bulk measles component containing no preservative or adjuvant.

(iii) A frozen 5-milliliter sample of the smallpox component prior to any dilution or filtration.

(iv) A sample consisting of no less than sixteen 10-dose vials, or twelve 5-dose vials, or ten 50-dose vials of vaccine in final labeled containers, plus sufficient diluent in final labeled containers to reconstitute the vaccine.

(2) In addition to the requirements of paragraph (e)(1) of this section, whenever a new measles production seed lot is introduced, or whenever the source of measles cell culture subtrate must be reestablished and recertified, samples consisting of no less than 100 milliliters in 10-milliliter volumes, in a frozen state (−60° C), of the bulk measles component after clarification and containing stabilizer but no preservative or adjuvant, taken from each of 5 consecutive lots of the bulk vaccine.

(3) The product shall not be issued by the manufacturer until written notification of official release of each filling of each lot is received from the Director, Bureau of Biologics.

[38 FR 32068, Nov. 20, 1973, as amended at 40 FR 6779, Feb. 14, 1975; 41 FR 10430, Mar. 11, 1975; 42 FR 27582, May 31, 1977]

630.87 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted from those set forth in the additional standards relating to Measles-Smallpox Vaccine, Live (§§ 630.80 to 630.86, inclusive), shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood (Human)

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Subparts E—[Reserved]

Subpart F—Cryoprecipitated Antihemophilic Factor (Human)

640.50 Cryoprecipitated Antihemophilic Factor (Human).
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640.54 Processing.
640.55 U.S. Standard preparation.
640.56 Quality control test for potency.
640.57 Labeling.

Subpart G—Source Plasma (Human)

640.60 Source Plasma (Human).

present in the source blood from which the product was prepared.

(d) ABO blood group designation of the source blood.

(e) Donor number.

(f) Expiration date.

(g) The result of the serologic test for syphilis or the statement, "Nonreactive for Syphilis by STS".

(h) The result of the test for hepatitis B surface antigen or the statement "Non-reactive for HBsAg by FDA Required Test".

(i) Instructions to store the product as prescribed in § 610.53 of this chapter.

(j) A warning against further processing of the frozen product if there is evidence of breakage or thawing.

(k) Instructions to thaw the frozen product at a temperature between 30° and 37° C.

(l) Instructions to use the frozen product within 6 hours after thawing.

(m) Instructions to use a filter in the administration equipment.

(n) Instructions to administer ABO group compatible recipients.

(o) When applicable, a statement that the product should be gently and continuously agitated during storage.

(p) A statement to see the instruction circular for directions for use.

(q) The statement, "Caution: Federal Law Prohibits Dispensing Without a Prescription".

(r) Name, address and license number of the manufacturer.

(s) Where plasma has been prepared from Whole Blood (Human) processed by another licensed establishment, such fact, and the name, address, and license number of the other establishment.

(Secs. 201, 501, 502, Pub. L. 717, 52 Stat. 1040-1042 as amended, 1049-1051 as amended (21 U.S.C. 321, 351, 352); Secs. 361, Pub. L. 410, 58 Stat. 703 as amended (42 U.S.C. 264))

[42 FR 59878, Nov. 22, 1977, as amended at 43 FR 2148, Jan. 13, 1978]

EFFECTIVE DATE NOTE: (1) Section 640.35 becomes effective May 22, 1978. See 42 FR 59873, Nov. 22, 1978. (2) At 43 FR 2148, Jan. 13, 1978, paragraphs (b) through (r) were redesignated as paragraphs (c) through (s), and a new paragraph (b) was added, effective May 15, 1978.

Subpart E—[Reserved]

Subpart F—Cryoprecipitated Antihemophilic Factor (Human)

SOURCE: 42 FR 21774, Apr. 29, 1977, unless otherwise noted.

§ 640.50 Cryoprecipitated Antihemophilic Factor (Human).

(a) *Proper name and definition.* The proper name of this product shall be Cryopreciptated Antihemophilic Factor (Human). 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 Antihemophilic Factor (Human) 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) Plasmaphersis 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.

(c) Donors shall not be suitable if they are known to have been immunized by injection with human red blood cells within the last 6 months.

§ 640.52 Collection of source material.

(a) Whole blood used as a source of Cryoprecipitated Antihemophilic Factor (Human) shall be collected as prescribed in § 640.4, except that paragraphs (d) (2), (g), and (h) of that section shall not apply. Whole blood from which both Platelet Concentrate (Human) and Cryoprecipitated Antihemophilic Factor (Human) 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