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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 640**

[Docket No. 98N-0608]

**Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human); Confirmation in Part and Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; confirmation in part and technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is confirming in part the direct final rule that appeared in the **Federal Register** of May 14, 1999 (64 FR 26282). The direct final rule amends the biologics regulations by removing, revising, or updating specific regulations applicable to blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. FDA is confirming the provisions for which no significant adverse comments were received. The agency received significant adverse comments on certain provisions and is hereby amending Title 21 Code of Federal Regulations to reinstate the former provisions. In addition, FDA is correcting the precision of the value for protein concentration that was inadvertently omitted from the codified section of the direct final rule.

**DATES:** The effective date for the amendments to the sections published in the **Federal Register** of May 14, 1999 (64 FR 26282), and listed in table 1 of this document, is confirmed as September 27, 1999. The amendments to §§ 640.81(e) and (f), 640.92(a), and 640.102(e) are effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** FDA solicited comments concerning the direct final rule for a 75-day period ending July 28, 1999. FDA stated that the effective date of the direct final rule would be September 27, 1999, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA also stated that if a significant adverse comment applies to an amendment, paragraph, or section of the rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not subjects of significant adverse comments.

Thus, FDA is confirming in part the direct final rule (sections listed in table 1 of this document) effective September 27, 1999.

TABLE 1

21 CFR	Action
640.80(a) and (b)	Revised
640.81(c)	Revised
640.82(a) and (c)	Revised heading
640.82(d) and (e)	Revised
640.84	Revised introductory paragraph
640.84(a)	Removed introductory text
640.84(b)	Removed
640.84(a)(1) through (a)(4)	Redesignated as paragraphs (a) through (d)
640.84 new paragraphs (a) and (d)	Revised
640.90(a) and (b)	Revised
640.91(b)(2), (c), (e), and (f)	Revised
640.92(a)	Revised
640.92(c)	Revised heading
640.92(d) and (e)	Revised
640.94(a)	Revised
640.100(a), (b), and (c)	Revised
640.101(b)	Revised heading
640.101(e)(3), (e)(4), and (f)	Removed
640.103(b)	Revised
640.104(b)(2), (b)(3), (c)(1), and (c)(2)	Revised

Secondly, FDA received significant adverse comments on three provisions of the rule, 21 CFR 640.81(e) and (f) and 640.102(e). Therefore, the agency is amending these sections to reinstate the former provisions. Comments received by the agency regarding the reinstated portions of the rule will be applied to the corresponding portion of the companion proposed rule (64 FR 26344,

May 14, 1999), and will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

Finally, FDA is amending § 640.92(a) to include a revision of range for protein concentration. This change was discussed in the preamble to the Direct final rule (section III.G (64 FR 26282 at 26284)), but was inadvertently omitted from the codified section of the document.

### **List of Subjects in 21 CFR Part 640**

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on May 14, 1999 (64 FR 26282), is confirmed in part and 21 CFR part 640 is amended as follows:

### **PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS**

1. The authority citation for 21 CFR part 640 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Section 640.81 is amended by revising the last sentence in paragraph (e) and paragraph (f) to read as follows:

#### **§ 640.81 Processing.**

\* \* \* \* \*

(e) \* \* \* Heat treatment shall be conducted so that the solution is heated for not less than 10 or more than 11 hours at an attained temperature of 60°±0.5 °C.

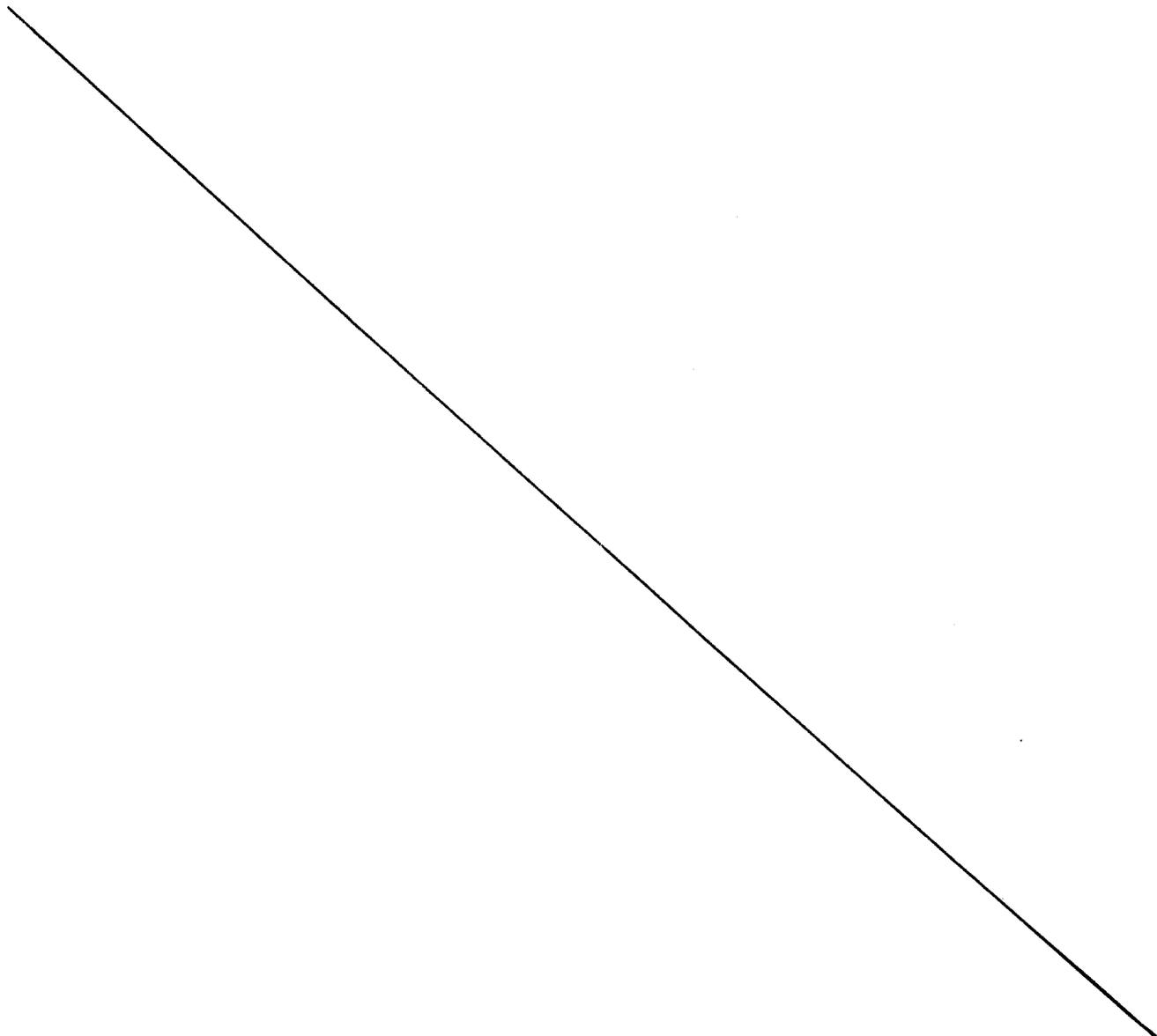
(f) *Stabilizer*. Either 0.16 millimole sodium acetyltryptophanate, or 0.08 millimole sodium acetyltryptophanate and 0.08 millimole sodium caprylate shall be added per gram of albumin as a stabilizer.

\* \* \* \* \*

**§ 640.92 [Amended]**

3. Section 640.92 *Tests on final product* is amended in paragraph (a) by removing “5.0±0.3” and adding in its place “5.0±0.30”.

4. Section 640.102 is amended by revising the last sentence of paragraph (e) to read as follows:



§ 640.102 Manufacture of Immune Globulin (Human).

\* \* \* \* \*

(e) \* \* \* At no time during processing shall the product be exposed to temperatures above 45 °C and after sterilization the product shall not be exposed to temperatures above 30 to 32 °C for more than 72 hours.

Dated: 3/8/00  
March 8, 2000



Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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