PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding an entry under the headings ''List of Substances'' and ''Limitations'' to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of Substances	Limitations
* * *	* * * *
Polyamidoamine-ethyleneimine-epichlorohydrin resin prepared by reacting hexanedioic acid, *N*-(2-aminoethyl)-1,2-ethanediamine, (chloromethyl)oxirane, ethyleneimine (aziridine), and polyethylene glycol, partly neutralized with sulfuric acid (CAS Reg. No. 167678–45–7).	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.12 percent resin by weight of the finished dry paper or paperboard.
* * *	* * * *

* * * * *

Dated: March 3, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–6116 Filed 3–13–00; 8:45 am]

BILLING CODE 4160–01–F

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.

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applicable to blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements.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 March 14, 2000.

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

TABLE 1—Continued

21 CFR	Action
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;deg;±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: March 8, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–6170 Filed 3–13–00; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1340

[Docket No. NHTSA–98–4280]

RIN 2127–AH46

Uniform Criteria for State Observational Surveys of Seat Belt Use

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This document adopts uniform criteria for State seat belt use surveys, previously published as an interim final rule, with one clarifying change in response to a comment. The criteria are used by the States to determine their seat belt use rates under a new Federal grant program, which directs the Secretary of Transportation to allocate funds to States whose seat belt use rates meet certain requirements, based on measurement criteria established by the Secretary.

EFFECTIVE DATE: April 13, 2000.

FOR FURTHER INFORMATION CONTACT: The following persons at the National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, D.C. 20590: For program issues, John F. Oates, Jr., State and Community Services, NSC–01, (202) 366–2121; For legal issues, John Donaldson, Office of the Chief Counsel, NCC–30, (202) 366–1834.

SUPPLEMENTARY INFORMATION:

A. Background

Section 1403 of the Transportation Equity Act for the 21st Century (Pub. L.105–178) added a new Section 157 to Title 23 of the United States Code (replacing a predecessor Section 157). The new provision (hereafter, Section 157) authorizes a State seat belt incentive grant program covering fiscal years 1999 through 2003. Under this program, the Secretary of Transportation is directed to allocate funds to the States, beginning in fiscal year 1999, based on their seat belt use rates. Specifically, Section 157 requires the Secretary to allocate funds to States that achieve a seat belt use rate in the preceding two years that is higher than the national average use rate or, failing that, a seat belt use rate that is higher than the highest seat belt use rate achieved by the State during specified previous calendar years. (Section 157 contains another provision for allocation of grant funds, based on innovative projects, but that provision is not addressed in this rule.)

Beginning with calendar year 1998, Section 157 requires States to measure seat belt use rates following criteria established by the Secretary, to ensure that the measurements are ''accurate and representative.'' In accordance with that mandate, NHTSA published an interim final rule on September 1, 1998, the Uniform Criteria for State Observational Surveys of Seat Belt Use, setting forth criteria for States to follow in determining their seat belt use rates under this program.