

Approved: March 13, 1998.

Samuel H. Banks,

Acting Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 610, 640, and 1270

Foods and Drugs; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct certain errors that have become incorporated into the biologics regulations. This action is being taken to improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: April 6, 1998.

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: FDA has discovered that certain errors have become incorporated into the agency's codified regulations on biologics. FDA is correcting these errors. These corrections are nonsubstantive.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

Lists of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 1270

Communicable diseases, HIV/AIDS, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 606, 610, 640, and 1270 are amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 606.121 [Amended]

2. Section 606.121 *Container label* is amended in paragraph (e)(1)(ii) by removing "expressd" and adding in its place "expressed".

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

3. The authority citation for 21 CFR part 610 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.

§ 610.30 [Amended]

4. Section 610.30 *Test for Mycoplasma*, lines 12, 13, 31, and 33 are amended by removing the period after the capital "C" each time it occurs.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

5. 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.

§ 640.2 [Amended]

6. Section 640.2 *General requirements* is amended in paragraph (e)(3) by removing the period after the capital "C".

§ 640.17 [Amended]

7. Section 640.17 *Modifications for specific products* is amended by removing the period after the capital "C".

§ 640.24 [Amended]

8. Section 640.24 *Processing* is amended in the first sentence in paragraph (b) by removing the phrase "between 20 to 24 °C" and adding in its place "between 20 and 24 °C".

§ 640.64 [Amended]

9. Section 640.64 *Collection of blood for Source Plasma* is amended in paragraph (c)(2) by adding a subscript "7" after the first "O" in "Citric acid".

§ 640.69 [Amended]

10. Section 640.69 *General requirements* is amended in paragraph (b) by removing the period after the capital "C".

§ 640.70 [Amended]

11. Section 640.70 *Labeling* is amended in paragraph (a)(3) by removing the period after the capital "C".

§ 640.74 [Amended]

12. Section 640.74 *Modification of Source Plasma* is amended in paragraph (b)(2) by removing the period after the capital "C".

§ 640.101 [Amended]

13. Section 640.101 *General requirements* is amended in paragraph (a) by removing the period after the capital "C".

§ 640.102 [Amended]

14. Section 640.102 *Manufacture of Immune Globulin (Human)* is amended in the second and third sentences in paragraph (c) and in the second sentence in paragraph (e) by removing the period after the capital "C" each time it occurs.

§ 640.104 [Amended]

15. Section 640.104 *Potency* is amended in paragraph (a) by removing the period after the capital "C".

PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

16. The authority citation for 21 CFR part 1270 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

§ 1270.33 [Amended]

17. Section 1270.33 *Records, general requirements* is amended in paragraph (b)(1) by removing "or" and adding in its place "and".

Dated: March 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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