

considered the sponsor of the program under this section.

By the Commission.

Dated: March 24, 1997.

Margaret H. McFarland,

Deputy Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 184, 529, and 610

Food 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 typographical and other inadvertent errors. This action is being taken to clarify and improve the accuracy of the regulations.

EFFECTIVE DATE: April 1, 1997.

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

SUPPLEMENTARY INFORMATION: FDA has discovered certain nonsubstantive errors that have been incorporated into the agency's codified regulations. FDA is correcting these errors. The errors in the regulations are as follows:

1. In 21 CFR 5.89(b)(1) "x-ray" is corrected to read "x-ray".

2. In 21 CFR 184.1(a) the phrase "of this chapter of" in the third sentence is corrected to read "of this chapter or".

3. In 21 CFR 529.50(c)(2) "*Klebsiella* spp." is corrected to read "*Klebsiella* spp.".

4. In 21 CFR 610.53(c), in the table, in the entry for "Rubella Virus Vaccine Live," in the third column, under the heading "Manufacturer's storage period 0 °C or colder (unless otherwise stated)," "°C" is corrected to read "do".

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.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 184

Food ingredients.

21 CFR Part 529

Animal drugs.

21 CFR Part 610

Biologics, Labeling, 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 5, 184, 529, and 610 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701-1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u-300u-5, 300aa-1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591.

§ 5.89 [Amended]

2. Section 5.89 *Notification of defects in, and repair or replacement of, electronic products* is amended in paragraph (b)(1) by removing "x-ray" and adding in its place "x-ray".

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

§ 184.1 [Amended]

4. Section 184.1 *Substances added directly to human food affirmed as generally recognized as safe (GRAS)* is amended in the third sentence in paragraph (a) by removing the phrase "of this chapter of" and adding in its place the phrase "of this chapter or".

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.50 [Amended]

6. Section 529.50 *Amikacin sulfate intrauterine solution* is amended in paragraph (c)(2) by removing "*Klebsiella* spp." and adding in its place "*Klebsiella* spp."

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

7. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

§ 610.53 [Amended]

8. § 610.53 *Dating periods for licensed biological products* is amended in the table in paragraph (c), in the entry for "Rubella Virus Vaccine Live," in the third column, under the heading "Manufacturer's storage period 0 °C or colder (unless otherwise stated)," by removing "°C" and adding in its place "do".

Dated: March 25, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

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21 CFR Part 310

[Docket Nos. 91P-0186 and 93P-0306]

Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of January 15, 1997 (62 FR 2218). The final rule amended the regulations to require label warning statements on products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes and to require unit dose packaging for iron-containing products that contain 30 milligrams or more of iron per dosage unit. The final rule was published with some typographical errors. This document corrects those errors.

DATES: Effective July 15, 1997.

FOR FURTHER INFORMATION CONTACT: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3101.

SUPPLEMENTARY INFORMATION: