considered the sponsor of the program under this section.

By the Commission.

Dated: March 24, 1997.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–8075 Filed 3–28–97; 8:45 am]

BILLING CODE 8010–01–P

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-reay'' 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* ssp.'' 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-reay'' 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* ssp.'' 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.

[FR Doc. 97–7971 Filed 3–28–97; 8:45 am]

BILLING CODE 4160–01–F

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:

In FR Doc. 97–947, beginning on page 2218 in the **Federal Register** of January 15, 1997, the following corrections are made in § 310.518 *Drug products containing iron or iron salts*:

§ 310.518 [Corrected]

1. On page 2250, in the second column, in paragraph (b)(2), beginning in the fourth line, the phrase ''the provisions of § 111.50(a) of this chapter'' is corrected to read ''the provisions of paragraph (a) of this section''.

2. On page 2250, in the third column, in paragraph (c)(5), in the second line, the phrase ''paragraph (b)(1) of this section'' is corrected to read ''paragraph (c)(1) of this section''.

Dated: March 25, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–7970 Filed 3–28–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 520 and 558

Animal Drugs, Feeds, and Related Products; Ronnel; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove that portion of the regulations reflecting approval of new animal drug applications (NADA's) held by Moorman Manufacturing Co. and Pitman-Moore, Inc., that provide for the use of ronnel oral dosage forms and ronnel Type A medicated article. The approval of these NADA's were previously withdrawn. This action is necessary to ensure the accuracy and consistency of the regulations.

EFFECTIVE DATE: March 31, 1997.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: FDA has discovered that certain errors have been incorporated into the agency's codified regulations on animal drugs. The errors in the regulations addressed in this document follow.

In a notice published in the **Federal Register** of July 19, 1989 (54 FR 30268), the agency announced that Pitman-Moore, Inc., had requested that FDA withdraw NADA's 12–360 and 12–361. In a final rule published in that same issue of the **Federal Register** (54 FR 30205), the agency inadvertently omitted an amendment to the regulations to remove § 520.2080 (21 CFR 520.2080).

In a notice published in the **Federal Register** of June 18, 1990 (55 FR 24646), the agency announced that Moorman Manufacturing Co. had requested that FDA withdraw NADA 13–450. In a final rule published in that same issue of the **Federal Register** (55 FR 24556), the agency inadvertently omitted an amendment to the regulations to remove § 558.525 (21 CFR 558.525).

At this time, the agency is correcting these errors. Accordingly, §§ 520.2080 and 558.525 are removed because the sections no longer represent approved products.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.2080 [Removed]

2. Section 520.2080 *Ronnel oral dosage forms* is removed.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.525 [Removed]

4. Section 558.525 *Ronnel* is removed.

Dated: March 4, 1997.

Linda Tollefson,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 97–8048 Filed 3–28–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Tylosin; 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 December 24, 1996 (61 FR 67713). The document amended the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The approved use level of tylosin Type C medicated swine feed was inadvertently omitted from the document. The document also contained certain editorial errors. This document corrects those errors.

EFFECTIVE DATE: December 24, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

In FR Doc. 96–32549, appearing on page 67713 in the **Federal Register** of Tuesday, December 24, 1996, the following correction is made:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.625 [Corrected]

2. On page 67713, in the second column, § 558.625 is amended by revising paragraph (f)(1)(vi)(*e*) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(1) * * *

(vi) * * *

(*e*) *Amount per ton.* Tylosin 100 grams.

(*1*) *Indications for use.* Prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* As tylosin phosphate, administer for 21 days.

Dated: February 6, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–8049 Filed 3–28–97; 8:45 am]

BILLING CODE 4160–01–F