listed in § 133.175; pasteurized cheese spread with fruits, vegetables, or meats as defined in § 133.176; pasteurized process cheese spread as defined in § 133.179; pasteurized process cheese spread with fruits, vegetables, or meats as defined in § 133.180 of this chapter.

(d) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1) of this chapter. The current good manufacturing practice level is the quantity of the ingredient that delivers a maximum of 250 parts per million of nisin in the finished product as determined by the British Standards Institution Methods, "Methods for the Estimation and Differentiation of Nisin in Processed Cheese," BS 4020 (1974), which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, RM. 4-62, 5600 Fishers Lane, Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

Dated: March 25, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-7459 Filed 4-5-88; 8:45 am]

BILLING CODE 4160-01-M

21 CFR PART 558

New Animal Drugs for Use in Animal Feeds; Lasalocid and Oxytetracycline; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that amended the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Hoffman-La Roche, Inc., providing for the safe and effective use of a Type C cattle feed manufactured from separately approved lasalocid sodium and oxytetracycline (monoalkyl trimethyl ammonium salt) Type A articles (52 FR 48095; December 18, 1987). The supplementary information in the final rule inadvertently omitted the approved level of 100-gram-per-pound oxytetracycline (monoalkyl trimethyl ammonium salt). This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: In FR Doc 87-29036, appearing on page 48095 in the Federal Register of Friday, December 18, 1987 (52 FR 48095), in the second column under the heading "Supplementary Information" in the ninth line, the phrase "10- or 50-" should read "10-, 50-, or 100-".

Dated: March 31, 1988.

Richard A. Carnevale,

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

[FR Doc. 88-7525 Filed 4-5-88; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 800, 803, 807, 808, 809, 812, 813, 820, 860, 861, 864, 866, 876, 895, 1002, 1005, 1010, 1020, 1030, 1040, and 1050

[Docket No. 87N-0373]

Medical Device and Radiological Health Regulations; Editorial Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain of its regulations on medical device and radiological health to correct cross-references and typographical errors and to update the titles and mailing symbols of certain organizational units. This action will improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: April 6, 1988.

FOR FURTHER INFORMATION CONTACT: T. Rada Proehl, Regulations Editorial Staff (HFC-222), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: FDA is revising certain of its regulations on medical devices and radiological health to correct cross-references and typographical errors, to update the titles and mailing symbols of certain organizational units, and to clarify the regulations. The affected regulations are 21 CFR 800.12(c) (the second time it appears), 803.33(b), 807.22(a), 807.35(b), 807.37 (a) and (b)(2), 807.90(a), 807.95(c)(1), 808.87(a), 809.5(a) (1), (2), (3), and (4) and (b), 812.2(e), 812.19, 812.20 (b)(9) and (d), 812.38(d), 813.20(a), 813.38 (b) and (c), 813.119(e)(2), 813.160, the introductory text of paragraph (a), 820.1(d), 820.3(f), 860.7(g)(4), 860.123(b)(1), 861.32 (b) and (c)(5), 864.9050(a), 864.9160(a), 866.5240(a), 866.5890(a), 876.5830(a), 895.21(d)(1), 1002.7, 1002.10, text of the introductory paragraph, 1002.20(a), the introductory text of paragraph (b), and (b)(5), 1002.31(c), 1002.41(a)(1), 1002.50, the introductory text of paragraph (a) and (b), 1002.51, 1005.11, 1005.25 (b) and (c), 1010.2 (c) and (d), 1010.3 (a)(1) and (2)(i), (b), and (c), 1010.4, the introductory text of paragraph (a), (b)(1)(viii), and (c) (1) and (3), 1010.5, the introductory text of paragraph (a), (b), (c)(12), and (e) (1) and (2), 1010.13, 1020.30 (c), (d), and (d)(3)(ii), 1020.32(a)(1), 1030.10(c) (4)(iv), (5)(iv), and (6)(iii), the introductory text of (c)(6)(iv), and (c)(6)(iv)(*d*), 1040.30(c)(1)(ii), and 1050.10(d)(5).

Because these amendments are nonsubstantive, notice and public procedure and delayed effective date are unnecessary (5 U.S.C. 553 (b)(B) and (d)).

List of Subjects

21 CFR Part 800

Administrative practice and procedure, Medical devices, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 803

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 809

Labeling, Medical devices.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 813

Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 861

Administrative practice and procedure, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 864

Blood, Biologics, Laboratories, Medical devices, Packaging and containers.

21 CFR Part 866

Blood, Biologics, Laboratories, Medical devices.

21 CFR Part 876

Medical devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

21 CFR Part 1005

Administrative practice and procedure, Electronics products, Imports, Radiation protection, Surety bonds.

21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Television, X-Rays.

21 CFR Part 1030

Electronic products, Microwave ovens, Radiation protection.

21 CFR Part 1040

Electronic products, Lasers, Medical devices, Radiation protection.

21 CFR Part 1050

Electronic products, Sonic, Infrasonic, and Ultrasonic products, Medical devices, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Radiation Control for Health and Safety Act of 1968, and under authority delegated to the Commissioner of Food and Drugs, Parts 800, 803, 807, 808, 809, 812, 813, 820, 860, 861, 864, 866, 876, 895, 1002, 1005, 1010, 1020, 1030, 1040, and 1050 are amended as follows:

PART 800—GENERAL

1. The authority citation for 21 CFR Part 800 is revised to read as follows and the authority citations following all the sections in Part 800 are removed:

Authority: Secs. 201(n), 304, 501, 502, 505, 506, 507, 515, 519, 521, 601, 602, 701 (21 U.S.C. 321(n), 334, 351, 352, 355, 356, 357, 360e, 360i, 360k, 361, 362, 371).

§ 800.12 [Amended]

2. Section 800.12 *Contact lens solutions and tablets: tamper-resistant packaging* is amended by removing paragraph (c) the second time it appears.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR Part 803 continues to read as follows:

Authority: Secs. 502(t), 510, 519, 701(a), 704 (a) and (e), 52 Stat. 1055, 76 Stat. 792–795 as amended, 90 Stat. 564–565, 578, 581 (21 U.S.C. 352(t), 360, 360i, 371(a), 374 (a) and (e)).

§ 803.33 [Amended]

4. Section 803.33 *Where to submit a report* is amended in paragraph (b) by revising "Device Monitoring Branch" to read "Product Monitoring Branch".

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS OF DEVICES

5. The authority citation for 21 CFR Part 807 continues to read as follows:

Authority: Secs. 301(p), 501, 502, 510, 513, 701(a), 52 Stat. 1049–1051 as amended, 1055, 76 Stat. 794–795 as amended, 86 Stat. 462 as amended, 90 Stat. 540–546 (21 U.S.C. 331(p), 351, 352, 360, 360c, 371(a)); 21 CFR 5.10.

§ 807.22 [Amended]

6. Section 807.22 *How and where to register establishments and list devices* is amended in paragraph (a) by revising "Bureau of Medical Devices (HFK–124)" to read "Center for Devices and Radiological Health (HFZ–342)".

§ 807.35 [Amended]

7. Section 807.35 *Notification of registrant* is amended in paragraph (b) by revising "Bureau of Biologics" and "Bureau of Drugs" to read "Center for Biologics Evaluation and Research" and "Center for Drug Evaluation and Research", respectively, everywhere they appear.

§ 807.37 [Amended]

8. Section 807.37 *Inspection of establishment registration and device listings* is amended in paragraphs (a) and (b)(2) by revising "Bureau of Medical Devices (HFK–124)" to read "Center for Devices and Radiological Health (HFZ–342)".

§ 807.90 [Amended]

9. Section 807.90 *Format of a premarket notification submission* is amended in paragraph (a) by revising "Bureau of Medical Devices (HFK–20)" to read "Center for Devices and Radiological Health (HFZ–401)".

§ 807.95 [Amended]

10. Section 807.95 *Confidentiality of information* is amended in paragraph (c)(1) by revising "§ 807.87(g)" to read "§ 807.87(h)".

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

11. The authority citation for 21 CFR Part 808 continues to read as follows:

Authority: Secs. 521, 701, 52 Stat. 1055–1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371); 21 CFR 5.10.

§ 808.87 [Amended]

12. Section 808.87 *Oregon* is amended in paragraph (a) by revising "§ 801.420(a)(b)" to read "§ 801.420(a)(6)".

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

13. The authority citation for 21 CFR Part 809 continues to read as follows:

Authority: Sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371).

§ 809.5 [Amended]

14. Section 809.5 *Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act* is amended in paragraphs (a) (1), (2), (3), and (4) and (b) by removing "Form 5 or Form 6".

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

15. The authority citation for 21 CFR Part 812 continues to read as follows:

Authority: Secs. 301, 501, 502, 520, 701(a), 702,704, 801, 52 Stat. 1042–1043 as amended, 1049–1051 as amended, 1055, 1056–1058 as amended, 67 Stat. 476–477 as amended, 90 Stat. 565–574 (21 U.S.C. 331, 351, 352, 360j, 371(a), 372, 374, 381); 21 CFR 5.10.

§ 812.2 [Amended]

16. Section 812.2 *Applicability* is amended in paragraph (e) by revising "investigational new drug exemption" to read "investigational new drug application".

§ 812.19 [Amended]

17. Section 812.19 *Address for IDE correspondence* is amended by revising "Bureau of Medical Devices, Document Control Center (HFK–20)" to read "Center for Devices and Radiological Health, Document Mail Center (HFZ–401)".

§ 812.20 [Amended]

18. Section 812.20 *Application* is amended in paragraph (b)(9) by