

Chlamydia psittaci sensitive to chlortetracycline.

(iii) **Limitations:** Feed continuously for 45 days. As chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride. Each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. **Warning:** "Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials."

Effective date: March 18, 1983.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 8, 1983.

Lester M. Crawford,
Director, Bureau of Veterinary Medicine.
[FR Doc. 83-6879 Filed 3-17-83; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for Zip Feed Mills, Inc., providing for safe and effective use of 2-gram-per-pound and 10-gram-per-pound tylosin premixes for making complete swine feeds.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: Zip Feed Mills, Inc., P.O. Box 500, 304 E. Eighth St., Sioux Falls, SD 57101, is the sponsor of supplemental NADA 97-259 submitted on its behalf by Elanco Products Co. The supplement provides for making 2-gram-per-pound and 10-gram-per-pound tylosin premixes. The premixes are used to make complete swine feeds for use as provided for in 21 CFR 558.625(f)(1)(vi) (a), (b), (c), and (d). The firm currently holds approval for making 0.4, 4, and 10-gram-per-pound tylosin premixes for swine feeds for use as provided for in 21 CFR 558.625(f)(1)(vi) (a).

Approval of this supplement relies upon safety and effectiveness data contained in Elanco's approved NADA 12-491. Elanco authorizes use of the

data in NADA 12-491 to support this supplement. This approval does not change the approved use of the drug. Consequently, approval poses no increased human risk of exposure to residues of the animal drug nor does it change the conditions of the drug's safe use in the target animal species.

Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64387; December 23, 1977), this is a Category II supplemental approval which does not require reevaluation of the safety and effectiveness data in NADA 12-491.

This supplement is approved and the regulations in 21 CFR 558.625 are amended accordingly.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24 (d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b)(18) to read as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.625 Tylosin.

(b) * * *

(18) To 017434: 0.4 and 4 grams per pound, paragraph (f)(1)(iv) (a) of this section; 2 and 10 grams per pound, paragraph (f)(1)(vi) (a) through (d) of this section.

* * *

Effective date: March 18, 1983
(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 11, 1983.

Robert A. Baldwin,
Associate Director for Scientific Evaluation.
[FR Doc. 83-6881 Filed 3-17-83; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 620

[Docket No. 78N-0425]

Typhoid Vaccine; Additional Standards; Correction

AGENCY: Food and Drug Administration.
ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting paragraph references that appeared in a final rule amending the biologics regulations to revise the additional standards for typhoid vaccine.

FOR FURTHER INFORMATION CONTACT: Agnes B. Black, Federal Register Writer (HFC-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: In FR Doc. 83-4196 at page 7165 in the Federal Register of Friday, February 18, 1983, the following corrections are made: At page 7168 in the first column in amendment "5." to § 620.14 *General requirements*, the reference to "paragraph (c)(1)" is changed to "paragraph (c)(2)"; and the reference to "paragraph (b)(2)" is changed to "paragraph (c)(3)."

Dated: March 9, 1983.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-6733 Filed 3-17-83; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 1003

[Docket No. 78N-0400]

Protection of Human Subjects; Informed Consent; Correction

AGENCY: Food and Drug Administration.
ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration is correcting an error in the conforming amendment on protection of human subject; informed consent which published in the Federal Register on January 27, 1981).

FOR FURTHER INFORMATION CONTACT: Melvyn R. Altman, National Center for Devices and Radiological Health (HFX-460), 12720 Twinbrook Parkway, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In FR Doc. 81-2687 at page 8942 in the Federal

Register of Tuesday, January 27, 1981, the following correction is made on page 8957: In § 1003.31 *Granting the exemption* in paragraph (b) in the first sentence, the phrase "significant risk to injury, including generic injury," is changed to "significant risk of injury, including genetic injury."

Dated: March 14, 1983.
William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.
[FR Doc. 83-7217 Filed 3-17-83; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Parts 1240 and 1250

Control of Communicable Diseases; Interstate Conveyance Sanitation; Editorial Amendments

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending editorially various sections of the regulations on control of communicable diseases and the regulations on interstate conveyance sanitation in Parts 1240 and 1250 (21 CFR Parts 1240 and 1250) to correct recodification errors and update references.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: Malcolm B. Reddoch, Bureau of Foods (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202-245-3092.

SUPPLEMENTARY INFORMATION: In FR Doc. 75-3395 in the Federal Register of Thursday, February 6, 1975 (40 FR 5620), 21 CFR Parts 1240 and 1250 were added as recodified from 42 CFR Part 72. Various nomenclature changes, cross-references, updates, and authority citations were omitted. This document makes the necessary changes. The changes are nonsubstantive.

List of Subjects

21 CFR Part 1240

Administrative practice and procedure, Communicable diseases, Foreign quarantine, Interstate conveyance sanitation, Shellfish, Water, potable.

21 CFR Part 1250

Administrative practice and procedure, Foreign quarantine, Interstate conveyance sanitation, Water, potable.

Therefore, under the Public Health Service Act (Sec. 361, 58 Stat. 703, as amended (42 U.S.C. 264)), the Federal Food, Drug, and Cosmetic Act (sec.

701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 1240 and 1250 are amended as follows:

PART 1240—CONTROL OF COMMUNICABLE DISEASES

1. The authority citation for Part 1240 is revised to read as follows:

Authority: Secs. 215, 311, 361, 368, 58 Stat. 690, 693, 703, as amended, 706 (42 U.S.C. 216, 243, 264, 271).

2. A cross-reference section is added below the "source" citation to Part 1240, as follows:

Cross-References: For Department of Health and Human Services regulations relating to foreign quarantine, sanitation measures, and control of communicable diseases, see Centers for Disease Control's requirements as set forth in 42 CFR Parts 71 and 72; and within that Part 71 under § 71.602, the standards and source approval requirements cited under Part 72 are no longer codified thereunder as the applicable requirements of 42 CFR Part 72 having been recodified to 21 CFR Parts 1240 and 1250 in FR Doc. 75-3395 in the Federal Register of February 6, 1975 (40 FR 5620). Additionally, Food and Drug Administration regulations relating to interstate conveyance sanitation are prescribed in Part 1250 of this chapter.

§ 1240.3 [Amended]

3. In § 1240.3 *General definitions*, in paragraph (k), by changing "Public Health Service Drinking Water Standards as set forth in 42 CFR 72.201 through 72.207" to "Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR Part 141 and the Food and Drug Administration's sanitation requirements as set forth in this Part and Part 1250 of this chapter."

§ 1240.20 [Amended]

4. In § 1240.20 *Issuance and posting of certificates following inspections*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1240.30 [Amended]

5. In § 1240.30 *Measures in the event of inadequate local control*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1240.62 [Amended]

6. In § 1240.62:

a. By revising the section heading to read "Turtles, intrastate and interstate requirements." (This change is also to be made in the table of contents to Part 1240.)

b. In paragraph (c)(1)(ii), at the end of the first sentence, after "Food and Drug Administration," by adding "200 C St. SW., Washington, DC 20204."

c. By removing the authority citation "(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))" at the end of the section.

§ 1240.80 [Amended]

7. In § 1240.80 *General requirements for water for drinking and culinary purposes*, by changing "Surgeon General" to "Commissioner of Food and Drugs" in the two places it appears.

§ 1240.83 [Amended]

8. In § 1240.83 *Approval of watering points*:

a. In paragraph (a), by revising the introductory text and (a)(1) to read "(a) The Commissioner of Food and Drugs shall approve any watering point if (1) the water supply threat meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR Part 141, and";

b. In paragraph (b), by changing "Surgeon General" to "Commissioner of Food and Drugs."

c. In paragraph (c), by changing "Surgeon General" to "Commissioner of Food and Drugs."

d. In paragraph (d), by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1240.90 [Amended]

9. In § 1240.90 *Approval of treatment aboard conveyances*:

a. In paragraph (a), by changing "Surgeon General" to "Commissioner of Food and Drugs."

b. In paragraph (b), by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1240.95 [Amended]

10. In § 1240.95 *Sanitation of water boats*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

PART 1250—INTERSTATE CONVEYANCE SANITATION

11. The authority citation for Part 1250 is revised to read as follows:

Authority: Secs. 215, 311, 361, 368, 58 Stat. 690, 693, 703, as amended, 706 (42 U.S.C. 216, 243, 264, 271).

12. A cross-reference section is added below the "source" citation to Part 1250, to read as follows:

Cross-References: For Department of Health and Human Services regulations relating to foreign quarantine and control of communicable diseases, see Centers for Disease Control's requirements as set forth in 42 CFR Parts 71 and 72; and within that Part 71 under § 71.602, the standards and source approval requirements cited under Part 72 are no longer codified thereunder as the applicable requirements of 42 CFR Part 72

having been recodified to 21 CFR Parts 1240 and 1250 in FR Doc. 75-3395 in the Federal Register of February 6, 1975 (40 FR 5620). Additionally, Food and Drug Administration regulations relating to interstate conveyance sanitation are prescribed in Part 1250 of this chapter.

§ 1250.3 [Amended]

13. In § 1250.3 *Definitions*, in paragraph (j) by changing "Public Health Service Drinking Water Standards as set forth in 42 CFR 72.201 through 72.207" to "Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR Part 141 and the Food and Drug Administration's sanitation regulations as set forth in this Part and Part 1240 of this chapter."

§ 1250.21 [Amended]

14. In § 1250.21 *Inspection*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.25 [Amended]

15. In § 1250.25 *Source identification and inspection of food and drink*:

a. In paragraph (a), by changing "Surgeon General" to "Commissioner of Food and Drugs."

b. In paragraph (b), by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.26 [Amended]

16. In § 1250.26 *Special food requirements*, in paragraph (a) by changing "Surgeon General" to "Commissioner of Food and Drugs" in the three places it appears.

§ 1250.41 [Amended]

17. In § 1250.41 *Submittal of construction plans*, by changing "Surgeon General" to "Commissioner of Food and Drugs" in the two places it appears.

§ 1250.51 [Amended]

18. In § 1250.51 *Railroad conveyances; discharge of wastes*:

a. In paragraph (d) in the first sentence by inserting "Sub-Program Manager" after "Bureau of Foods," by removing "Branch"; and by changing "HFF-324" to "HFF-312."

b. In paragraph (f)(3) in the first sentence by inserting "Sub-Program Managers," after "Bureau of Foods"; by removing "Branch"; and by changing "HFF-324" to "HFF-312."

c. By removing the authority citation, "(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))" at the end of the section.

d. By adding the following cross-reference at the end of the section:

Cross-Reference: For statutory exemptions

for "intercity rail passenger service," see section 306(i) of 45 U.S.C. 546(i).

§ 1250.52 [Amended]

19. In § 1250.52 *Discharge of wastes on highway conveyances*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.53 [Amended]

20. In § 1250.53 *Discharge of wastes on air conveyances*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.60 [Amended]

21. In § 1250.60 *Applicability*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.61 [Amended]

22. In § 1250.61 *Inspection and approval*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.62 [Amended]

23. In § 1250.62 *Submittal of construction plans*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.81 [Amended]

24. In § 1250.81 *Inspection*, by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.82 [Amended]

25. In § 1250.82 *Potable water systems*, in paragraph (f) by changing "Surgeon General" to "Commissioner of Food and Drugs."

§ 1250.93 [Amended]

26. In § 1250.93 *Discharge of wastes*:
a. By changing "Surgeon General" to "Commissioner of Food and Drugs."

b. By adding the following cross-reference at the end of the section:

Cross-Reference: For Environmental Protection Agency's regulations for vessel sanitary discharges as related to authority under the Federal Water Pollution Control Act, as amended (33 U.S.C. 1314 et seq.), see 40 CFR Part 140.

Effective date: March 18, 1983.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)); sec. 361, 58 Stat. 703, as amended (42 U.S.C. 264))

Dated: March 15, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-7245 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 885

[Docket No. R-82-982]

Housing for the Elderly or Handicapped; Amendment To Implement Cost Savings Procedures

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This final rule revises 24 CFR Part 885, Loans for Housing for the Elderly or Handicapped, to adopt the cost limits from the Section 221(d)(3) mortgage insurance program for Section 202 projects, to require competitive bidding on construction contracts except in certain specified instances, and to simplify cost certification procedures.

EFFECTIVE DATE: May 2, 1983, except the information collection requirements of § 885.415, which are under review at OMB. The effective date for these information requirements will be announced by separate notice in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Robert W. Wilden, Director, Elderly Cooperative, Congregate and Health Facilities Division, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, D.C. 20410, (202) 426-8730. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background of Rule

On May 11, 1982, HUD published an interim rule to implement cost savings procedures in the development of multifamily dwellings for the elderly under Section 202 of the Housing Act of 1959. It involved four issues: (1) Competitive bidding for all Section 202 construction contracts exceeding \$100,000; (2) simplified cost certification by borrowers in small projects; (3) increased minimum capital investment from one-half of one percent of the mortgage amount, not to exceed \$10,000, to 1 percent of the mortgage amount, not to exceed \$25,000; and (4) amendment to the per unit cost limits to conform them to those used for nonprofit borrowers in the Section 221(d)(3) mortgage insurance program.

On June 2, 1982, the Banking, Finance and Urban Affairs Committee of the House of Representatives, pursuant to