§ 212.25 Further proceedings.

(a) Ordinarily, the determination of an award will be made on the basis of the written record. However, on request of either the applicant or the Commission investigative attorney, or on his or her own initiative, the presiding officer may in his or her discretion order further proceedings, such as an informal conference, oral argument, additional written submissions or an evidentiary hearing. Such further proceedings shall be held only when necessary for full and fair resolution of the issues arising from the application, and shall be conducted as promptly as possible.

(b) A request that the presiding officer order further proceedings under this section shall specifically identify the information sought or the disputed issues and shall explain why the additional proceedings are necessary to resolve the issues.

§ 212.26 Determination.

The presiding officer shall issue a recommended determination on the application within 90 days after completion of proceedings on the application. The determination shall include written findings and conclusions on the applicant's eligibility and status as prevailing party, and an explanation of the reasons for any difference between the amount requested and the amount awarded. The determination shall also include, if at issue, findings on whether the position of the Commission investigative attorney was substantially justified, whether the applicant unduly protracted the proceedings, or whether special circumstances make an award unjust.

§ 212.27 Agency review.

Except as otherwise authorized by the presiding officer, the parties shall be allowed ten (10) days from the date of service of the recommended determination to file exceptions to the recommended determination and alternative findings of fact and conclusions of law with the Commission. Upon receipt of the recommended determination, the Commission shall review the same and issue a final determination on the application or remand the application to the presiding officer for further proceedings.

§ 212.28 Judicial review.

Judicial review of final Commission determinations on awards may be sought as provided in 5 U.S.C. 504(c)(2).

§ 212.29 Payment of award.

An applicant seeking payment of an award shall submit to the Finance and Budget Division of the Commission a copy of the Commission's final determination granting the award, accompanied by a statement that the applicant will not seek review of the decision in the United States courts. The address for submission to the Commission is: United States International Trade Commission, Finance and Budget Division, 701 E Street, NW., Washington, D.C. 20436. The Commission will pay the amount to the applicant within 60 days, unless judicial review of the award or of the underlying determination of the adversary adjudication has been sought by the applicant or any other party to the proceeding.

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: February 23, 1982.

[FR Doc. 82-5784 Filed 3-4-82; 8:45 am]

BILLING CODE 7020-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 Quali-Tech Products, Inc., providing for safe and effective use of 1, 2, 4, 8, and 10-gram-per-pound tylosin premixes for making complete swine, beef cattle, and chicken feeds.

EFFECTIVE DATE: March 5, 1982.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318, is sponsor of supplemental NADA 97-980 submitted on its behalf by Elanco Products Co. The supplement provides for use of premixes containing 1, 2, 4, 8, and 10 grams of tylosin (as tylosin phosphate) per pound for making complete feeds for swine, beef cattle, and layer chickens. The swine feed is used for prevention, treatment, and control of swine dysentary, and for maintenance of weight gain and promotion of feed efficiency in the presense of atrophic rhinitis; the beef cattle feed for reduction of incidence of certain liver abscesses; the chicken feed for increased rate of weight gain and improved feed efficiency; the layer feed for improved feed efficiency.

Approval of this supplemental NADA relies upon safety and effectiveness data contained in Elanco Products Co.'s approved NADA 12-491. Use of the data in NADA 12-491 to support this supplement has been authorized by Elanco. This approval does not change the approved use of the drug. Consequently, approval of this supplement poses no increased human risk from 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 64367; 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 or NADA 97-980.

The supplement is approved, and the regulations are amended accordingly. This approval adds to the firm's existing approval for use of 4- and 10-gram-per-pound tylosin premixes for making complete swine feeds for increased rate of weight gain and improved feed efficiency.

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.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is excluded from Executive Order 12291 by section 1(a)(1) of the Order.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)), under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1, see 46 FR 26052, May 11, 1981)), and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b)(14) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(14) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraph (f)(1) (i), (iii), (iv), and (vi) of this section.

* * * * *

Effective date. March 5, 1982.

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

Dated: February 24, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-5650 Filed 3-4-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 175

[Docket No. 81F-0113]

Indirect Food Additives: Adhesive Coatings and Components; Hydrocarbon Resins

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of certain hydrocarbon resins as a component of adhesives intended for food contact. This action is based on a food additive petition filed by Hercules, Inc.

DATES: Effective March 5, 1982; objections by April 5, 1982.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: A notice published in the Federal Register of April 28, 1981 (46 FR 23810) announced that a food additive petition (FAP 0B3501) had been filed by Hercules, Inc., 910 Market St., Wilmington, DE 19899, proposing that § 175.105 (21 CFR 175.105) be amended to provide for the safe use of hydrocarbon resins formed by polymerization of mixtures of mono- and di-unsaturated hydrocarbons of the aliphatic, alicyclic, and monobenzenoid type derived both from cracked petroleum and terpene stocks as a component of adhesives intended for food contact.

FDA has evaluated data in the petition and other relevant material, and concludes that the proposed food additive use is safe and that the regulations should be amended as set forth below. In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact and the evidence supporting this finding, contained in a statement of exemption (pursuant to 21 CFR 25.1(f)(1)(v)) may be seen in the Dockets Management Branch (HFA-305) (address above) between 9 a.m. and 4 p.m., Monday through Friday.

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 175 is amended in § 175.105(c)(5) by alphabetically inserting a new item in the list of substances to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Hydrocarbon resins (produced by polymerization of mixtures of mono- and di-unsaturated hydrocarbons of the aliphatic, alicyclic, and monobenzenoid type derived both from cracked petroleum and terpene stocks) (CAS Reg. No. 68239-99-6)	
* * * * *	

Any person who will be adversely affected by the foregoing regulation may at any time on or before April 5, 1982 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective March 5, 1982.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

Dated: February 23, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-5651 Filed 3-4-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 211, 331, 436, 450, 520, 556, 573, 610, 630, 701, and 801

[Docket No. 81N-0266]

Incorporation by Reference Regulatory Text

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the incorporating regulatory text in Title 21 of the Code of Federal Regulations to make clear when an incorporation by reference is intended. This action is being taken to meet the drafting requirements for incorporation by reference as set forth in Title 1 of the Code of Federal Regulations (1 CFR Part 51).

DATES: Effective March 5, 1982; written comments by April 5, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Theodore E. Herman, Regulations Policy Staff (HFC–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3480.

SUPPLEMENTARY INFORMATION: Title 1 of the Code of Federal Regulations (1 CFR 51.6, 51.7, and 51.8) requires, in addition to other information, specific language in a regulation that makes clear that an incorporation by reference is intended.

FDA has reviewed all of its regulations that include materials incorporated by reference. The agency has concluded that it is necessary to amend a number of these regulations to bring them into compliance with the drafting requirements prescribed in 1 CFR 51.6, 51.7, and 51.8.

The agency is amending Parts 211, 331, 436, 450, 520, 556, 573, 610, 630, 701, and 801 to include language that: clearly indicates that an incorporation by reference is intended; contains a complete citation of the material incorporated; and contains a statement about the availability of the incorporated material. These amendments ensure compliance with the essential requirements specified in 1 CFR 51.6, 51.7, and 51.8.

Therefore, under 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 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Title 21 of the Code of Federal Regulations is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

§ 211.176 [Amended]

1. Section 211.176 is amended by revising the last sentence and adding a new sentence to read "Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in 'Procedures for Detecting and Measuring Penicillin Contamination in Drugs,' which is incorporated by reference. Copies are available from the Bureau of Drugs (HFD–430), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

§ 331.22 [Amended]

2. Section 331.22 is amended at the end of the paragraph by removing footnote "1" and by replacing the period with a comma and adding "which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

§ 436.101 [Amended]

3. Section 436.101(a) is amended at the end of the introductory text by removing footnote "2" and by replacing the colon with a comma and adding "which is incorporated by reference. Copies are available from the Medical Encyclopedia Inc., 30 East 60th St., New York, NY 11220, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

§ 436.102 [Amended]

4. Section 436.102(b) is amended in the introductory text (1) in the first sentence by removing footnote "2" and by replacing the period with a comma and adding "which is incorporated by reference. Copies are available from Medical Encyclopedia Inc., 30 East 60th St., New York, NY, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408" and (2) in the last sentence by removing footnote "3" and by replacing the period with a comma and adding "which is incorporated by reference. Copies are available from the American Pharmaceutical Association, 2215 Constitution Ave. NW., Washington, D.C. 20037, or available for inspection at the Office of the Federal Register (see address in this paragraph)."

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

§ 450.20a [Amended]

5a. Section 450.20a(b)(4)(ii) is amended at the end of the last sentence by removing footnote "2" and by replacing the period with a comma and adding "which is incorporated by reference. Copies are available from Managing Editor, 'Biometrics,' P.O. Box 5457, Raleigh, NC 27607, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

§ 450.24 [Amended]

b. Section 450.24(b)(5)(ii) is amended at the end of the last sentence by removing footnote "4" and by replacing the period with a comma and adding "which is incorporated by reference. Copies are available from Managing Editor, 'Biometrics,' P.O. Box 5457, Raleigh, NC 27607, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

§ 450.240 [Amended]

c. Section 450.240(b)(4)(ii) is amended at the end of the last sentence by removing footnote "2" and by replacing the period with a comma and adding "which is incorporated by reference. Copies are available from the American Statistical Association, 806 15th St. NW., Washington, D.C. 20005, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

6. Section 520.2320 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 520.2320 Sulfanitran and aklomide in combination.

* * * * *

(b) * * *

(1) * * *

(iii) Moisture (Method No. 6.123, "Toluene Distillation Method—Official Final Action" in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, p. 83. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408): Not more than 2.0 percent.

* * * * *

PART 556—TOLERANCES FOR RESIDUE OF NEW ANIMAL DRUGS IN FOOD

§ 556.240 [Amended]

7a. Section 556.240(b) is amended by revising that portion of the paragraph

beginning with "method of E. J. Umberger" to read "method of E. J. Umberger, G. H. Gass, and J. M. Curtis, 'Design of A Biological Assay Method for the Detection and Estimation of Estrogenic Residues in the Edible Tissues of Domestic Animals Treated with Estrogens' published in *Endocrinology*, 63:806–814, 1958, which is incorporated by reference. Copies are available from the Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

§ 556.250 [Amended]

b. Section 556.250(b) is amended by revising that portion of the paragraph beginning with "method of E. J. Umberger" to read "method of E. J. Umberger, G. H. Gass, and J. M. Curtis, 'Design of A Biological Assay Method for the Detection and Estimation of Estrogenic Residues in the Edible Tissues of Domestic Animals Treated with Estrogens,' published in *Endocrinology*, 63:806–814, 1958, which is incorporated by reference. Copies are available from the Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

§ 556.540 [Amended]

c. Section 556.540(b) is amended in the introductory text by revising that portion of the paragraph beginning with "method of Hooker and Forbes" to read "method of Hooker and Forbes, 'A Bio-Assay for Minute Amounts of Progesterone,' published in *Endocrinology*, 41:158–168, 1947. Copies are available from Yale University, Department of Anatomy, New Haven, CT 06520, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

§ 556.710 [Amended]

d. Section 556.710(b) is amended at the end of the paragraph by removing footnote "1" and replacing the period with a comma and adding "which is incorporated by reference. Copies are available from Academic Press Inc., 111 Fifth Ave., New York, NY 10003, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

8. Section 573.640 is amended by revising paragraph (b)(4)(i) and the first sentence of (b)(4)(ii) and adding after it a new sentence to read as follows:

§ 573.640 Methyl esters of higher fatty acids.

* * * * *

(b) * * *

(4) * * *

(i) Unsaponifiable matter shall be determined by the method described in Section 28.081, "Unsaponifiable Residue (20)—Official Final Action" of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, p. 451, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(ii) The chick-edema factor bioassay method described under "26. Oils, Fats, and Waxes" in the *Journal of the Association of Official Agricultural Chemists*, Vol. 44, Page 146 (1961), or the method described under "Chick-Edema Factor—Bioassay Method (34)—Official Final Action" in §§ 28.113–28.117, "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975, pp. 509–511, which is incorporated by reference, shall be employed. (Copies of the methods are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.) * * *

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

§ 610.12 [Amended]

9. Section 610.12(f) is amended in the first sentence by revising that portion of the sentence that reads "United States Pharmacopeia[1] (19th Revision, 1975), section entitled 'Membrane Filtration,' pp. 594–595, except that" to read "United States Pharmacopeia (19th revision, 1975, section entitled 'Membrane Filtration,' pp. 594–595, which is incorporated by reference (Copies are available from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), except that * * *" and by removing footnote "1".

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

§ 630.74 [Amended]

10. Section 630.74(c) is amended in the first sentence by removing footnote "1" and at the end of the third sentence by replacing the period with a comma and adding "or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408."

PART 701—COSMETIC LABELING

§ 701.3 [Amended]

11a. Section 701.3(c)(2)(i) is amended by revising the introductory text to read "(i) CTFA (Cosmetic, Toiletry, and Fragrance Association, Inc.) Cosmetic Ingredient Dictionary, Second Ed., 1977 (available from The Cosmetic, Toiletry, and Fragrance Association, Inc., 1110 Vermont Ave. NW., Suite 800, Washington, DC 20005, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), which is incorporated by reference, except for the following deletions and revisions:"

b. Section 701.3(c)(2)(ii), (iii), and (v) is amended by removing footnote "2" and adding at the end of the last sentence of each subparagraph "(Copies are available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408)."

c. Section 701.3(c)(2)(iv) is amended at the end of the paragraph by removing footnote "3" and by adding "Copies are available from the Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

PART 801—LABELING

§ 801.410 [Amended]

12a. Section 801.410(d)(2) is amended near the end of the paragraph by removing footnote "1" and by changing "ASTM Method D 1415" to read "ASTM Method D 1415–68 'Test for International Hardness of Vulcanized Rubber,'; by changing "ASTM Method D 412 to read "ASTM Method D 412–68 'Tension Test of Vulcanized Rubber,' the first time it appears; and by revising the phrase "as determined by ASTM Method D 412 (ASTM Methods D 412 and D 1415 are incorporated by reference)" to read "as determined by ASTM Method D 412–68 (Both methods are incorporated by reference and are available from the American Society for Testing Materials,

1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408)."

§ 801.420 [Amended]

b. Section 801.420(c)(4) is amended at the end of the second sentence by removing footnote "1", replacing the period with a comma, and adding "which is incorporated by reference. Copies are available from the Acoustical Society of America, 335 E. 45th St., New York, NY 10017, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408."

The agency has determined that because these amendments do not make any substantive changes in the regulations but merely are editorial, bringing the incorporation by reference text into compliance with the drafting requirements of 1 CFR 51.6, 51.7, and 51.8, notice public procedure, and delayed effective date are unnecessary. However, interested persons may, on or before April 5, 1982 submit to the Dockets Management Branch (HFA-305), address above, written comments regarding these amendments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments shall be identified with the docket number found in brackets in the heading of this document. If the agency determines by the comments received that the amended text should be modified, a notice containing those modifications will be published in the **Federal Register**. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 1, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-5459 Filed 3-4-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification: Tylosin Injection

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the new animal drug regulation for tylosin injection at the request of Elanco Products Co., the sponsor. The labeling revisions clarify directions for use in cattle and swine.

EFFECTIVE DATE: March 5, 1982.

FOR FURTHER INFORMATION CONTACT: Richard A. Carnevale, Bureau of Veterinary Medicine (HFV-125), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1788.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 2, 1981 (46 FR 48642), FDA approved a supplemental new animal drug application (NADA 12-965) providing for increasing the withdrawal period and dosage for use of tylosin injection in cattle and swine. The regulation stated that the drug was approved for "nonlactating cattle." Elanco has requested that the regulation be clarified by changing it to read "beef cattle and nonlactating dairy cattle." The regulation also directed use of the 50-milligram-per-milliliter preparation to "nonlactating cattle weighing less than 200 pounds." Elanco requested that this description be changed to "calves." Also, the regulation provided the same limitation for swine weighing less than 200 pounds. Elanco requested that this limitation be removed. The changes are approved.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(ii) (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.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

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 (formerly 5.1; see 46 FR 26052; May 11, 1981)) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended in § 522.2640a by revising the introductory text of paragraph (e)(1) and the fourth sentence of (e)(1)(iii) to read as follows, and by removing the fourth sentence of (e)(2)(iii) which reads "Use a 50-milligram-per-milliliter solution for treating swine weighing less than 200 pounds."

§ 522.2640a Tylosin injection.

* * * * *

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—* * *

(iii) * * * Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. * * *

* * * * *

Effective date: This regulation is effective March 5, 1982.

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

Dated: February 26, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-5801 Filed 3-4-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline, Monensin

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 new animal drug application (NADA) filed by American Cyanamid Co. providing for safe and effective use of chlortetracycline hydrochloride in combination with monensin in broiler feeds as an aid in reduction of mortality due to *Escherichia coli* and prevention of coccidiosis.

EFFECTIVE DATE: March 5, 1982.

FOR FURTHER INFORMATION CONTACT: Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-149), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: American Cyanamid Co., Berdan Ave., Wayne, NJ 07470, filed an NADA (121-553) providing for use of a combination finished broiler feed containing 500 grams of chlortetracycline hydrochloride per ton with 90 to 110 grams of monensin (as monensin sodium) per ton. The feeds are used as an aid in the reduction of mortality due to *Escherichia coli* infections susceptible to such treatment and as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.* The application is approved and the regulations are amended to reflect the approval.

The approval of this combination is subject to the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977).