[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Redelegation of Grants Authority

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Commissioner of Food and Drugs is amending the regulations for delegations of authority by decentralizing the authority to approve or disapprove applications for grants and redelegating the authority to bureau level officials. The action, part of a decentralization effort to move operational functions out of the Office of the Commissioner, is being taken to increase the effectiveness of operations.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: Section 5.25 (21 CFR 5.25) is being revised by deleting the delegation of authority and reference to the Associate and Deputy Associate Commissioner for Science. Approval authority for grant applications is being delegated to bureau directors, the Executive Director of Regional Operations, and the Director, National Center for Toxicological Research, and the authority to execute and issue notices of grant awards is extended to include the Chief of the Grants Management Branch of the new Office of Management and Operations.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting," or unless not legally permissible.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and secs. 301, 307, 311, and 356 of the Public Health Service Act (42 U.S.C. 241, 242l, 243, and 263d) and under authority delegated to the Commissioner (21 CFR 5.1), part 5 is amended by revising § 5.25 to read as follows:

§ 5.25 Grants.

(a) The directors of bureaus, the Executive Director of Regional Operations, and the Director of the National Center for Toxicological Research are authorized to approve or disapprove applications for grants under sections 301, 307, and 311 of the Public Health Service Act.

(b) The Director of the Bureau of Radiological Health is authorized to approve or disapprove applications for grants under section 356 of the Public Health Service Act.

(c) The Associate and Deputy Associate Commissioner for Management and Operations, the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Management and Operations, and the Chief of the Grants Management Branch of that Division and Office are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof.

Effective date. This regulation shall be effective July 28, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)) and secs. 301, 307, 311, 356 (42 U.S.C. 241, 242l, 243, 263d).)

Dated: July 24, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-20864 Filed 7-27-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of two new animal drug applications (NADA's) providing for use of 10-gram-per-pound tylosin premixes for making complete swine feeds. The applications were filed by Feed Service Co. and Illini Feeds. The list of sponsors is also amended to establish entries for these firms.

EFFECTIVE DATE: July 28, 1278.

FOR FURTHER INFORMATION CONTACT:

Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: Feed service Co., Inc., Box 876, Mankato, Minn. 56001, and Illini Feed, Box T, Oneida, Ill. 61467, filed NADA's 111-637V and 110-202V to provide for 10-gram-per-pound tylosin (as tylosin phosphate) premixes to be used for subsequent manufacture of complete swine feeds. The complete feeds would increase rate of weight gain and improve feed efficiency. Approval of these applications relies upon safety and effectiveness data contained in Elanco Products Co.'s approved NADA 12-491V (see §558.625(f)(1)(vi)(a) (21 CFR 558.625(f)(1)(vi)(a))). The approvals do not constitute reaffirmation of Elanco Products Co.'s NADA nor do they constitute reaffirmation of the drug's safety and effectiveness.

In accordance with the freedom of information regulations and §514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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 Foods and Drugs (21 CFR 5.1), parts 510 and 558 are amended as follows:

1. In part 510, §510.600 is amended by adding two new sponsors alphabetically to paragraph (c)(1) and numerically to paragraph (c)(2), to read as follows:

§510.600 Names, addresses, and code numbers of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug listing No.
* * * * *	
Feed Service Co., Inc., Box 876, Mankato, Minn. 56001	030841
* * * * *	
Illini Feeds, Box T, Oneida, Ill. 61467	037310
* * * * *	

(2) * * *

Drug listing No.	Firm name and address
*	* * * * *
030841	Feed Service Co., Inc., Box 876, Mankato, Minn. 56001.
*	* * * * *
037310	Illini Feeds, Box T, Oneida, Ill. 61467.
*	* * * * *

2. In part 558, §558.625 is amended by adding new paragraph (b) (54) and (55) to read as follows:

§558.625 **Tylosin.**

* * * * *

(b) * * *

(54) To 030841: 10 grams per pound: paragraph (f)(1)(vi)(*a*) of this section.

(55) To 037310: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

* * * * *

Effective date: This regulation is effective July 28, 1978.

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

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20720 Filed 7-27-78; 8:45 am]

[4110-03]

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

Piperazine Phosphate-Thenium Closylate Tablets

AGENCY. Food and Drug Adminstration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by Jensen-Salsbery Laboratories, providing for use of a combination anthelmintic (drug used to destroy or expel intestinal worms) in treating weaned pups and dogs.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Jensen-Salsbery Laboratories, Division of Richardson-Merrell, Inc., 520 West 21st Street, Kansas City, Mo. 64141, filed an NADA (101-161V) providing for use of piperazine phosphate with thenium closylate tablets in weaned pups and adult dogs for removal of certain hookworms and ascarids.

In accordance with the freedom of information regulations and §514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the Office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

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 5.1), part 520 is amended by adding new §520.1805, to read as follows:

§520.1805 **Piperazine phosphate with thenium closylate tablets.**

(a) *Specifications.* Each scored tablet contains the equivalent of 250 milligams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams thenium (as thenium closylate).

(b) *Sponsor.* See No. 017220 in §510.600(c) of this chapter.

(c) *Conditions of use.*—(1) *Amount.* Administer orally to dogs as follows:

NUMBER OF TABLETS AT EACH OF THE TWO DOSES

Animal weight (lb):	
2 but less than 5	½
5 but less than 10	1
10 or heavier	2

(2) *Indications for use.* For removal of immature (fourth stage larvae) and adult hookworms (*Ancylostoma caninum, A. braziliense,* and *Uncinaria stenocephala*) and ascarids (*Toxocara canis*) from weaned pups and adult dogs.

(3) *Limitations.* Do not use this product to treat dogs weighing less than 2 pounds, unweaned pups, or pups under 5 weeks of age. Maximum efficacy against hookworms necessitates two doses in 1 day of treatment. The interval between the doses should be not less than 4 hours or more than 24 hours. Administer the first dose in the morning before feeding. Do not permit dog to chew tablet. Feed the dog between doses. Do not feed milk or other fatty foods during treatment. Retreatment may be needed in 7 to 28 days as determined by laboratory fecal examinations or in animals kept in known contaminated quarters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date: July 28, 1978.

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

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20723 Filed 7-27-78; 8:45 am]

[4110-03]

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

Uredofos Tablets; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect the change of sponsor for uredofos tablets from Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., to Beecham Laboratories, Division of Beecham, Inc. A supplemental new animal drug application (NADA) filed by Beecham Laboratories provides for this change.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, Tenn. 37620, filed a supplemental new animal drug application (NADA 100-745V) providing for the change of sponsor for uredofos tablets.

This intercorporate transfer of an NADA does not involve changes in manufacturing, packaging, or quality control. The approval does not require a reevaluation of the parent NADA nor does it constitute a reaffirmation of the drug's safety or effectiveness.

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 5.1), §520.2645 *Uredofos tablets* is amended in paragraph (c) by deleting the number "011794" and inserting in its place the number "000029."

Effective date: This regulation is effective July 28, 1978.

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

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20725 Filed 7-27-78; 8:45 am]

[4110-03]

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

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

Procaine Penicillin G Aqueous Suspension (Injectable)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) providing revised labeling of injectable procaine penicillin G aqueous suspension used in treating certain infections of cattle, sheep, swine, and horses. The application was filed by Pfizer, Inc., in compliance with the National Academy of Sciences—National Research Council Drug Efficacy Study Group (NAS/NRC) evaluation of the product. This document also amends the regulations by establishing a zero residue tolerance for penicillin and its salts in sheep.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Myron C. Rosenberg, Bureau of Veterinary Medicine (HFV-125), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-1788.

SUPPLEMENTARY INFORMATION: Pfizer's product was one of several mentioned in the NAS/NRC evaluation published in the FEDERAL REGISTER of August 25, 1970 (35 FR 13544). In that document, the NAS/NRC concluded, and the Food and Drug Administration (FDA) concurred, that these products were probably effective for intramuscular use in treating infections in animals caused by pathogens sensitive to procaine penicillin. The NAS/NRC stated:

1. The dosage directions are inadequate. The dosage should be so expressed as to provide a specific quantity of the drug per unit of body weight per unit of time for each animal species.

2. The minimum allowable dosage should range from 3,000 to 10,000 units per pound body weight per day depending on the animal species. In some diseases, because of decreasing bacterial sensitivity, higher doses may be necessary.

3. Properly qualify disease entities as to those caused by pathogens sensitive to penicillin. If the disease claim cannot be so qualified the claim must be dropped.

4. The labeling should not recommend injection into open wounds, abscesses, and actinomycotic lesions, nor should the labeling recommend increasing the dose if there is no response to previous injections.

5. The labeling should state the recommended procedure for treating hyper- sensitivity reactions to penicillin and also the occasional hypersensitivity to procaine.

6. The labeling should provide a precaution statement indicating the need for sensitivity testing preceding the use of penicillin in treating staphylococcal pathogens.

7. The residue warnings should be updated.

The NAS/NRC evaluation was concerned only with the drug's effectiveness and safety to the animal being treated and did not take into account the safety of food derived from treated animals.

The evaluation was published to inform NADA holders of the findings of the NAS/NRC and FDA and to inform all interested persons that such articles may be marketed, provided they are the subject of approved NADA's and otherwise comply with the requirements of the Federal Food, Drug, and Cosmetic Act. NADA's that pertain to identical products and reflect those conditions of use as set forth in this regulation do not require efficacy data as specified by § 514.1(b)(8)(ii) or § 514.111(a)(5)(vi) of the animal drug regulations. In lieu of such data, approval may require bioequivalency or similar data as suggested in the guideline for submitting NADA's for NAS/NRC-reviewed generic drugs. The guideline is available from the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Those conditions of use are identified in this regulation by a footnote.

Pfizer, Inc., 235 East 42d Street, New York, N.Y. 10017, submitted a supplemental NADA (65-110V) which responded to the above-enumerated NASA/NRC recommendations as follows:

1. and 2. The recommended daily dosage in large animal species is now given in the product labeling as 3,000 units per pound of body weight. The indications for use of this product in all small animals have been removed from the labeling.

3. Disease entities have been qualified as to causative pathogen and these are sensitive to penicillin. Many disease claims and several animal species have been deleted from the indications of use. Indications for the use of this drug in the treatment of anthrax have been deleted from product labeling.

4. The labeling does not recommend injection into open wounds, abscesses, actinomycotic lesions nor does it suggest increasing the dose if there is no response to the previous dose. On the contrary the labeling warns against doses above those specifically recommended.

5. The revised labeling (package insert) provides a cautionary statement regarding untoward reactions that may occur in animals administered this drug and describes how they should be treated.

6. Indications for use of this product against diseases caused by *Staphylococcus spp.* have been deleted. Overgrowth of resist- ant organisms including fungi resulting from use of this product is described on the package insert.

7. Residue warnings have been updated in accordance with directions received from FDA in a letter dated April 28, 1976.

A dosage of 3,000 units per pound of body weight meets NAS/NRC efficacy requirements for treatment of the cattle, sheep, swine, and horse diseases set forth in the indications for use in this regulation.

These claim deletions and modifications in indications for use have substantiated upgrading the NAS/NRC rating from probably effective to effective.

Although this drug has been indicated for use in sheep for many years, a residue tolerance for this species has never been listed in § 556.510 (21 CFR 556.510). The FDA is currently reevaluating the tolerances for penicillins in all species. Pending completion of this evaluation, § 556.510 is being amended to include sheep among those species for which a zero tolerance is now in effect. This action does not constitute a reevaluation or reaffirmation of the underlying human safety data.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the Office of the Hearing Clerk HFA-305), at the above-named address from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

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 5.1), Parts 540 and 556 are amended as follows:

1. In part 540, § 540.274b is amended by adding new paragraph (c)(3) to read as follows:

§ 540.274b Procaine penicillin G aqueous suspension.

* * * * *

(c) * * *

(3)(i) *Specifications.* The drug conforms to the requirements prescribed