"Cloxacillin benzathine," the word "Do" is changed to read "Intraperitoneal" and in the entry for the antibiotic drug "Cloxacillin sodium monohydrate," the word "Do" is changed to read "Intravenous."

Dated: February 8, 1982.

William F. Randolph,

Acting Associate Commissioner, Regulatory Affairs.

[FR Doc. 82-3914 Filed 2-12-82; 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; Dexamethasone Sodium Phosphate Injection

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 John D. Copanos, Inc., providing for safe and effective use of a dexamethasone sodium phosphate injection in dogs and horses for its glucocorticoid and anti-inflammatory effect.

EFFECTIVE DATE: February 16, 1982.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: John D. Copanos, Inc., 6110 Robinwood Rd., Baltimore, MD 21225, filed an NADA (124-510) providing for intravenous use of a dexamethasone sodium phosphate injection in dogs and horses. The product contains 4 milligrams of dexamethasone sodium phosphate per milliliter and is administered for its adrenal glucocorticoid and anti-inflammatory effect.

The product is similar to Schering's Azium (dexamethasone sterile injection), a National Academy of Sciences/National Research Council (NAS/NRC) reviewed product, which was found effective as an anti-inflammatory agent in dogs, cats, horses, and cattle. Subsequently, Anthony Products' Dex-A-Vet Injection (dexamethasone sodium phosphate sterile injection) was approved as provided under 21 CFR 320.25(e) for the same conditions of use based on a bioavailability study. Both products are codified in 21 CFR 522.540. Copanos' product is approved based on its being identical to Anthony Products' approved product which has been found similar to the NAS/NRC reviewed product. The requirement for evidence of in vivo bioavailability has been waived under 21 CFR 320.22(b)(1). NADA 124-510 is approved and the regulation is amended appropriately.

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.

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.

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 § 522.540 by revising paragraph (e)(2) to read as follows:

§ 522.540 Dexamethasone injection.

* * * * *

(e) * * *

(2) *Sponsors.* See Nos. 015579 and 010271 in § 510.600(c) of this chapter.

* * * * *

Effective date. This regulation is effective February 16, 1982.

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

Dated: February 4, 1982.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 82-3759 Filed 2-12-82; 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; Praziquantel Injectable Solution

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 by Bayvet Division of Cutter Laboratories, Inc., providing for safe and effective subcutaneous or intramuscular use of praziquantel injectable solution for removal of certain cestodes from cats.

EFFECTIVE DATE: February 16, 1982.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Bayvet Division of Cutter Laboratories, Inc., P.O. Box 390, Shawnee, KS 66201, filed a supplemental NADA (111-607) providing for safe and effective use of praziquantel injectable solution (Droncit Injectable Cestocide) for removal of certain feline cestodes. Bayvet submitted results of several controlled critical preclinical studies demonstrating effectiveness of the drug in treating naturally and experimentally induced *D. caninum* and *T. taeniaeformis* infections in cats, and results of field studies using bunamidine hydrochloride as a positive control drug. Several controlled safety evaluations and clinical trials demonstrated safe use of the drug.

Based on the data and information submitted, the supplemental NADA is approved and the regulations are amended to reflect the approval. The firm currently holds approval for use of the drug for treating dogs as reflected in 21 CFR 522.1870.

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 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 Bureau'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)(ii)(*a*), (*e*)(1) and (*2*), and (iii)) which may be seen in the Dockets Management Branch (address above).

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 § 522.1870 by redesignating existing paragraph (c)(1), (2), and (3) as (c)(1)(i), (ii), and (iii), and by adding new (c)(1) heading and new (c)(2), to read as follows:

§ 522.1870 Praziquantel injectable solution.

* * * * *

(c) * * * (1) *Dogs.* * * *

(2) *Cats.*—(i) *Amount.* For cats under 5 pounds, 0.2 milliliter (11.4 milligrams); 5 to 10 pounds, 0.4 milliliter (22.7 milligrams); 11 pounds and over, 0.6 milliliter (34.1 milligrams) maximum.

(ii) *Indications for use.* For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis.*

(iii) *Limitations.* For subcutaneous or intramuscular injection only. Not intended for use in kittens less than 6 weeks of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This amendment is effective February 16, 1982.

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

Dated: February 4, 1982.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 82-3761 Filed 2-12-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Mibolerone

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) sponsored by The Upjohn Co. providing for safe and effective use of mibolerone in a canned dog food for the prevention of estrus (heat) in female dogs not intended primarily for breeding purposes.

EFFECTIVE DATE: February 16, 1982.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: The Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001, filed an NADA (107-347) which provides for safe and effective use of mibolerone in a canned dog food for the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

Approval of this NADA relies on safety and efficacy data in Upjohn's NADA 102-709, and clinical and nonclinical studies supporting use of the new formulation. The NADA is approved and the regulations are amended to reflect the approval.

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 therefore 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 (secs. 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 558 is amended by adding new § 558.348, to read as follows:

§ 558.348 Mibolerone.

(a) *Approvals.* To No. 000009 in § 510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

(b) *Conditions of use.*—(1) *Amount.* 30 micrograms for animals weighing up to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, or German Shepherds or German Shepherd mix weighing 30 to 80 pounds.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Administer daily at least 30 days before expected initiation of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This regulation is effective February 16, 1982.

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

Dated: February 4, 1982.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 82-3760 Filed 2-12-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 601

[Docket No. 78N-0400]

Protection of Human Subjects; Informed Consent; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting an omission that occurred inadvertently in the conforming amendments to the regulation on protection of human subjects; informed consent, which was published in the Federal Register of January 27, 1981 (46 FR 8942).

EFFECTIVE DATE: July 27, 1981.

FOR FURTHER INFORMATION CONTACT: Al Rothschild, Bureau of Biologics

(HFB–620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301–443–1306.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 27, 1981 (46 FR 8942), FDA published the regulation on protection of human subjects; informed consent and standards for institutional review boards for clinical investigations. In the conforming amendments to that regulation, a sentence was inadvertently omitted from § 601.2(a) (21 CFR 601.2(a)). This document corrects that omission.

PART 601—LABELING

§ 601.2 [Amended]

In FR Doc. 81–2687 appearing at page 8942 in the **Federal Register** of January 27, 1981, the following correction is made in the third column on page 8955: In § 601.2 *Applications for establishment and product licenses; procedures for filing,* in paragraph (a) the following sentence is added before the last sentence in the paragraph: "The applicant shall also include an environment impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the biological product pursuant to § 25.1 of this chapter."

Dated: February 8, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–3913 Filed 2–12–82; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 740

Relocation Assistance; Revised Interest Payments

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: Federal Highway Administration (FHWA), is issuing this amendment in order to change the discount rate used in computing an interest differential payment for homeowners displaced by Federal or federally assisted highway projects. This amendment eliminates the requirement that the discount rate must be the prevailing rate paid on passbook savings accounts.

EFFECTIVE DATE: March 22, 1982.

FOR FURTHER INFORMATION CONTACT: Gerald Starkweather, Relocation Assistance Division, Office of Right-of-Way (202–426–0117); or Reid Alsop, Office of the Chief Counsel (202–426–0800), Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours Monday–Friday from 7:45 a.m. to 4:15 p.m. ET.

SUPPLEMENTARY INFORMATION: Section 203(a)(1)(B) of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601 *et seq.*) provides that the replacement housing payment to displaced homeowners, provided by section 203, shall include "The amount, if any, which will compensate such displaced person for any increased interest costs which such person is required to pay for financing the acquisition of * * * comparable dwelling." The amount of such payment is to equal the total increase in cost for a mortgage of the same amount and term as was on the acquired dwelling, "reduced to discounted present value." Section 203 (a)(1)(B) provides that "the discount rate shall be the prevailing interest rate paid on savings deposits by commercial banks in the general area in which the replacement dwelling is located."

In implementing this provision FHWA provided in 23 CFR 740.74(c)(4) that the discount rate "shall be the prevailing rate of the interest paid on *passbook* savings account deposits by commercial banks in the general area in which the replacement dwelling is located." (Emphasis supplied.)

At the time the regulation was issued, interest rates for home mortgages were substantially lower, and the passbook savings rate was a reasonable rate to utilize. With the general escalation of interest rates and with the advent of the savings certificate and other types of savings deposits, and their increased popularity, it is considered necessary to eliminate the requirement that computation of the interest differential payment be based upon the interest rate paid on passbook savings. The current regulation, which limits the discount rate to that paid on passbook savings account deposits, has resulted in inordinately excessive interest differential payments in many cases.

The use of the passbook savings account rate of interest in computing the differential payment results in a final computed amount which is larger than if higher alternative rates (such as those paid by commercial banks on other types of savings deposits) could be used. Consequently, in certain instances displaced homeowners are currently provided differential payments which result in a windfall profit to such persons. In extreme cases use of the passbook rate can result in the computation of interest differential payments that exceed the unpaid balance of the displaced homeowner's mortgage. FHWA takes the position that, today, prudent and possibly conservative investors will select certificates of deposit, all-savers certificates or other higher rate deposit arrangements in lieu of passbook savings accounts, due to the much higher interest earned. Since passbook savings accounts no longer appear to attract the average saver, the 5½ percent discount rate embodied in the current regulation should be replaced by a higher rate which conforms to the present day financial market.

Accordingly, FHWA is amending 23 CFR 740.74(c)(4) to eliminate any reference to passbook savings accounts. Similar changes are being made in Appendix A to Part 740 which contains a "Format for Computation of Interest Payments." As amended, the regulation will be identical to the language in the statute.

This change gives the displacing agency the flexibility to utilize a discount rate based upon the interest rate paid on savings accounts other than passbook savings accounts, such as the rate paid on certificates of deposit by commercial banks. It is estimated that this change will reduce the average annual interest differential payments by approximately 40 percent.

Displaced homeowners will still be fully compensated for their increased interest costs, as required by the Uniform Relocation Act. This change merely eliminates unjustifiable windfalls that are possible under the current regulation because of the escalation of interest rates that have occurred since the regulation was promulgated.

Disposition of Comments

A notice of proposed rulemaking was published for comment in the **Federal Register** on September 14, 1981, (46 FR 45627). Twenty comments were received. These include seventeen from State highway agencies, one from a Federal agency, one from a city agency, and one from a consultant.

Comments generally expressed support for the proposed change in the regulation, or agreed that the regulation should be changed. Several of the comments recommended that the new mortgage should be reduced by the amount necessary to maintain the same monthly payment and term as the old mortgage, utilizing the new higher