

the establishment of a Public Board of Inquiry consisting of three qualified scientists from outside the agency (21 CFR Part 13).

Before a Board could be convened, however, preliminary results from an audit of the records of certain animal studies conducted by or for Searle, including studies on aspartame, indicated a need for a comprehensive review of the authenticity of the aspartame research data. As a result, pursuant to 21 U.S.C. 348(e), FDA formally stayed the regulation authorizing the marketing of aspartame (40 FR 56907, December 5, 1975). A comprehensive review was conducted, over the span of several years, after which FDA concluded that the aspartame data were indeed authentic.

On June 1, 1979, FDA announced the establishment of a Public Board of Inquiry (the Board) to help resolve the issues surrounding the proposed marketing of aspartame (44 FR 31716). The hearing was subsequently held on January 30 and 31, and February 1, 1980.

On October 1, 1980, the Board issued its decision and concluded that aspartame should not be marketed without further testing in order to resolve certain safety concerns. Pursuant to FDA regulations, the matter was then appealed to the Commissioner for a final agency decision.

In the *Federal Register* of July 24, 1981 (46 FR 38285), the Commissioner issued his Final Decision on the food additive petition for aspartame. The Commissioner overruled the Board and determined that aspartame had been shown to be safe for its proposed uses. The Commissioner announced that the stay of effectiveness of the regulation for aspartame (21 CFR 172.804) was vacated and that the regulation was reinstated (see item IX. 2. at 46 FR 38303; July 24, 1981).

#### **PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION**

##### **§ 172.804 [Reinstated]**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409 (c)(3)(A) and (f) (1) and (2), 72 Stat. 1786-1787 (21 U.S.C. 348 (c)(3)(A) and (f) (1) and (2))) and 21 CFR 12.130 and under authority delegated to the Commissioner (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), the stay of effectiveness for § 172.804 *Aspartame* is vacated and the regulation is reinstated.

*Effective date.* This regulation becomes effective October 22, 1981.

(Sec. 409 (c)(3)(A) and (f) (1) and (2), 72 Stat. 1786-1787 (21 U.S.C. 348 (c)(3)(A) and (f) (1) and (2)))

Dated: October 7, 1981.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 81-29791 Filed 10-15-81; 8:45 am]

**BILLING CODE 4110-03-M**

#### **21 CFR Part 520**

#### **Oral Dosage Form New Animal Drugs Not Subject to Certification; Oxibendazole Paste**

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the new animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Norden Laboratories, providing for use of oxibendazole paste for the removal of certain strongyles, roundworms, pinworms, and threadworms from horses.

**EFFECTIVE DATE:** October 16, 1981.

#### **FOR FURTHER INFORMATION CONTACT:**

Sandra K. Woods, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

**SUPPLEMENTARY INFORMATION:** Norden Laboratories, Lincoln, NE 68501, filed an NADA (121-042) providing for use of oxibendazole paste for horses for removal of certain large strongyles, small strongyles, large roundworms, threadworms, and pinworms (including various larval stages). The application is approved, and the regulations are amended to codify the approved use of this product.

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 submitted under 21 CFR 25.1(f)(1)(ii) (a) and (g) 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 520—ORAL 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 the 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 520 is amended by adding new § 520.1638, to read as follows:

##### **§ 520.1638 Oxibendazole paste.**

(a) *Specifications.* The paste contains 22.7 percent oxibendazole.

(b) *Sponsor.* See 011519 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* For uses other than for threadworms (*Strongyloides westeri*), 10 milligrams of oxibendazole per kilogram of body weight; for threadworms (*Strongyloides westeri*), 15 milligrams per kilogram.

(2) *Indications for use.* For removal and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*); small strongyles (genera *Cylicostephanus*, *Cylicocyclus*, *Cyathostomum*, *Triodontophorus*, *Cylicodontophorus*, and *Gyalocephalus*); large roundworms (*Parascaris equorum*); pinworms (*Oxyuris equi*) including various larval stages; and threadworms (*Strongyloides westeri*).

(3) *Limitations.* Administer orally by syringe. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Do not use in stallions at stud. Not for use in horses intended for food. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

*Effective date.* This regulation is effective October 16, 1981.

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

Dated: October 8, 1981.

**Terence Harvey,**

*Acting Director, Bureau of Veterinary Medicine.*

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## 21 CFR Part 520

**Oral Dosage Form New Animal Drugs Not Subject to Certification; Approval of Morantel Tartrate Bolus**

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 Pfizer, Inc., providing for safe and effective use of a bolus containing morantel tartrate as an anthelmintic in cattle.

EFFECTIVE DATE: October 16, 1981.

**FOR FURTHER INFORMATION CONTACT:** William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 E. 42nd St., New York, NY 10017, filed an NADA (93-903) providing for use of a morantel tartrate bolus for removal and control of mature gastrointestinal nematode infections of cattle. Pfizer has submitted data from safety and parasitological studies supporting the safety and effectiveness of morantel tartrate for this use. The NADA is approved and the regulations are amended accordingly.

Standards prescribed in the agency's proposal of March 20, 1979, (44 FR 17070) on chemical compounds in food-producing animals were not applied to approval of this NADA. The approval is based on alternative criteria which assure that the product is safe and on factors which justify the equitable treatment of this sponsor who completed drug development testing adequately according to scientific standards in existence before March 20, 1979.

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 an environmental impact analysis report (pursuant to 21 CFR 25.1(j)) 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.

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 (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 520—ORAL 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. 360(b)(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 520 is amended by adding new § 520.1450 to read as follows:

**§ 520.1450 Morantel tartrate bolus.**

(a) *Specifications.* Each bolus contains 2.2 grams morantel tartrate equivalent to 1.3 grams of morantel base.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use—(1) Amount.* One bolus per 500 pounds of body weight (4.4 milligrams per pound of body weight) as a single oral dose. Boluses may be divided in half for more accurate dosing as follows: up to 325 pounds, ½ bolus; 326 to 600 pounds, 1 bolus; 601 to 900 pounds, 1½ boluses; and 901 to 1,200 pounds, 2 boluses.

(2) *Indications for use.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(3) *Limitations.* Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism. Do not treat within 14 days of slaughter. Not for use in dairy animals of breeding age.

*Effective date.* October 16, 1981.

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

Dated: October 7, 1981.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 81-29633 Filed 10-15-81; 8:45 am]

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## 21 CFR PARTS 556 AND 558

**Establishment of Tolerances for Residues of New Animal Drugs in Food and New Animal Drugs for Use in Animal Feeds; Morantel Tartrate**

AGENCY: Food and Drug Administration.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc., providing for safe and effective use of a morantel tartrate premix in the manufacture of a finished feed to be used as an anthelmintic in cattle and to establish a tolerance for residues of morantel tartrate in edible tissues of cattle.

EFFECTIVE DATE: October 16, 1981.

**FOR FURTHER INFORMATION CONTACT:** William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 E. 42nd St., New York, NY 10017, filed an NADA (92-444) providing for use of morantel tartrate premix in the manufacture of a finished feed to be used for removal and control of mature gastrointestinal nematode infections of cattle. Pfizer has submitted data from safety and parasitological studies supporting the safety and effectiveness of morantel tartrate for this use. The NADA is approved and the regulations are amended accordingly.

Standards prescribed in the agency's proposal of March 20, 1979 (44 FR 17070) on chemical compounds in food-producing animals were not applied to approval of this NADA. The approval is based on alternative criteria which assure that the product is safe and on factors which justify the equitable treatment of this sponsor who completed drug development testing adequately according to scientific standards in existence before March 20, 1979.

Additionally, Pfizer submitted consumer safety related data from radiotracer metabolism, tissue residue depletion, and laboratory toxicology and pathology studies which support a preslaughter withdrawal period of 14 days for the labeled conditions of use.

The agency has accepted for regulatory purposes Pfizer's tissue residue method. Therefore, the regulations are further amended to establish cattle tolerances of 0.5 part per million (ppm) for residues in muscle, 1.0 ppm for liver, 1.5 ppm for kidney, and 2.0 ppm for fat.

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 an environmental impact analysis report (pursuant to 21 CFR 25.1(j)) may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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 (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.

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 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), Parts 556 and 558 are amended as follows:

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

1. Part 556 is amended by adding new § 556.425 to read as follows:

##### **§ 556.425 Morantel tartrate.**

Tolerances of 0.5 part per million (ppm) are established for total residues of morantel tartrate in uncooked cattle muscle, 1.0 ppm for liver, 1.5 ppm for kidney, and 2.0 ppm for fat. A drug residue assay measuring *N*-methyl-1, 3-propane diamine (the morantel fragment marker residue) in the target tissue, liver, serves to monitor the total residue in edible tissues. A marker residue concentration of 0.5 ppm in liver corresponds to 1.0 ppm in this target tissue.

#### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

2. Part 558 is amended by adding new § 558.360 to read as follows:

##### **§ 558.360 Morantel tartrate.**

(a) *Approvals.* Premix level of 88 grams per pound granted to 000069 in § 510.600(c) of this chapter.

(b) *Assay limits.* Finished feeds 85–115 percent of labeled amount. Premix 90–110 percent of labeled amount.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Special considerations.* (1) Do not mix in feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(e) *Conditions of use—(1) Amount.* 4.4 grams of morantel tartrate per pound of feed.

(2) *Indications for use.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(3) *Limitations.* Feed as a single therapeutic treatment at 0.1 pound of medicated ration (0.44 gram of morantel tartrate) per 100 pounds of body weight. Withhold feed overnight prior to treatment to insure the ration will be readily consumed. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Not for use in dairy cattle of breeding age. Do not treat animals within 14 days of slaughter.

*Effective date.* October 16, 1981.

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

Dated: October 7, 1981.

Gerald B. Guest,

*Acting Director, Bureau of Veterinary Medicine.*

[FR Doc. 81-29634 Filed 10-15-81; 8:45 am]

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#### **EQUAL EMPLOYMENT OPPORTUNITY COMMISSION**

##### **29 CFR Part 1602**

#### **Records and Reports; Elementary-Secondary Staff Information EEO-5; Waiver of Filing Reports for Calendar Year 1981**

**AGENCY:** Equal Employment Opportunity Commission.

**ACTION:** Waiver of Rule Requirement.

**SUMMARY:** The Equal Employment Opportunity Commission waives the EEO-5 filing requirement for calendar year 1981 in order to provide data which are usable in conjunction with the Department of Education, Office for Civil Rights student population survey, and to minimize impact on the respondent school districts. The Commission proposes to resume the EEO-5 on a biennial basis in 1982.

**EFFECTIVE DATE:** November 30, 1981.

**FOR FURTHER INFORMATION CONTACT:** Joachim Neckere, Chief, Survey Branch, Phone: (703) 756-6026.

**SUPPLEMENTARY INFORMATION:** The Equal Employment Opportunity Commission waives the requirement of § 1602.41 for filing the Elementary-Secondary Staff Information Report EEO-5 for the calendar year 1981. The recordkeeping requirements of § 1602.39 for calendar year 1981 remain unchanged and are not waived. The Commission reaffirms its filing requirements for these reports for calendar year 1982 and subsequent years.

**Note.**—Since the reporting requirement has been waived and no forms have been mailed to entities required to report, no further reporting action is required on 1981 reports.

Signed at Washington, D.C. this 8th day of Oct. 1981.

J. Clay Smith, Jr.,

*Acting Chairman, Equal Employment Opportunity Commission.*

[FR Doc. 81-30063 Filed 10-15-81; 8:45 am]

BILLING CODE 6570-06-M

#### **GENERAL SERVICES ADMINISTRATION**

##### **41 CFR Part 101-2**

[FPMR Amendment A-33]

#### **Payments to GSA for Supplies and Services Furnished Government Agencies; Billings, Payments, and Adjustments Reinstating the Use of the General Supply Fund in Financing Nonstock Requisitions**

**AGENCY:** General Services Administration.

**ACTION:** Final rule.

**SUMMARY:** This regulation specifies that the General Supply Fund (GSF) will be used to finance nonstock direct delivery requisitions for Government agencies. Agencies will continue to submit requisitions to GSA, where a purchase order will be initiated citing the GSF. Goods will be sent directly to the