

# Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

**AGENCY:** Food and Drug Administration, HHS.

**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 Merck Research Laboratories, Division of Merck & Co., Inc. The supplement provides for subcutaneous use of ivermectin injection as an antiparasitic in ranch-raised foxes.

**EFFECTIVE DATE:** August 30, 1995.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

**SUPPLEMENTARY INFORMATION:** Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, is sponsor of NADA 128-409 which provides for the use of Ivomec® Injection (ivermectin) as an antiparasitic for horses, cattle, reindeer, and swine. The supplement provides for use of 0.27 percent ivermectin as an antiparasitic for treatment and control of ear mites (*Otodectes cynotis*) in ranch-raised foxes. Approval is based in part on data and information in Public Master File (PMF) 5307 established under the National Research Support Project No. 7 (NRSP-7) (formerly the Interregional Research Project No. 4 (IR-4)), Northcentral Region, Michigan State University, East Lansing, MI 48824. The supplemental NADA is approved as of July 13, 1995, and the regulations are

amended in § 522.1192 (21 CFR 522.1192) to reflect the approval. The basis of approval is discussed in the freedom of information summary. Also, the heading of § 522.1192 is amended to read "Ivermectin injection."

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. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplement does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 522

Animal drugs  
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).  
2. Section 522.1192 is amended by revising the section heading, the

heading for paragraph (a)(3), and by adding new paragraph (d)(5) to read as follows:

#### § 522.1192 Ivermectin injection.

(a) \* \* \*

(3) *Piglets 70 pounds or less and ranch-raised foxes.* \* \* \*

\* \* \* \* \*

(d) \* \* \*

(5) *Ranch-raised foxes.* (i) *Amount.* 200 micrograms per kilogram body weight. Repeat in 3 weeks.

(ii) *Indications for use.* For treatment and control of ear mites (*Otodectes cynotis*).

(iii) *Limitations.* For subcutaneous use only. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: August 14, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-21454 Filed 8-29-95; 8:45 am]

BILLING CODE 4160-01-F

#### 21 CFR Part 529

#### Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Macleod Pharmaceuticals, Inc. The ANADA provides for the use of a generic gentamicin solution for control of bacterial infections of the uterus (metritis) of horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

**EFFECTIVE DATE:** August 30, 1995.

**FOR FURTHER INFORMATION CONTACT:** Sandra K. Woods, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1612.

**SUPPLEMENTARY INFORMATION:** Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525, is the sponsor of ANADA 200-115, which provides for the use of a generic gentamicin solution (100 milligrams/milliter (mg/mL)) for control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

Approval of ANADA 200-115 for Macleod Pharmaceuticals' gentamicin sulfate solution (100 mg/mL gentamicin) is as a generic copy of Schering's Gentocin® Solution (100mg/mL gentamicin) in NADA 046724. The ANADA is approved as of July 21, 1995, and the regulations are amended in 21 CFR 529.1044a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

#### PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

#### § 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended

in paragraph (b) by removing "000061, 057561, and 000856" and adding in its place "000061, 000856, 057561, and 058711".

Dated: August 14, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-21455 Filed 8-29-95; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Assistant Secretary for Community Planning and Development

#### 24 CFR Part 91

[Docket No. FR 3611-F-10]

### Consolidated Submission for Community Planning and Development Programs

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Final rule.

**SUMMARY:** As part of HUD's effort to consolidate and streamline submission requirements for the four formula grant programs, the Department published in the **Federal Register** on January 5, 1995, a final rule that consolidated into a single submission the planning and application aspects of the Department's Community Development Block Grant (CDBG), Emergency Shelter Grant (ESG), HOME Investment Partnerships (HOME), and Housing Opportunities for Persons with AIDS (HOPWA) programs. The purpose of this rule is to make an amendment to the deadline for submission of the Consolidated Plan in order to receive Community Development Block Grant funds.

**EFFECTIVE DATE:** September 29, 1995.

#### FOR FURTHER INFORMATION CONTACT:

James R. Broughman, Director, Office of Block Grant Assistance, Office of Community Planning and Development, 451 Seventh Street, SW., Washington, DC 20410-7000, telephone (202) 708-3587 (voice) or (202) 708-2565 (TDD). (These are not toll-free numbers.) Copies of this amendment will be made available on tape or large print for those with impaired vision that request them. They may be obtained at the above address.

**SUPPLEMENTARY INFORMATION:** On January 5, 1995 (60 FR 1878), the Department published in the **Federal Register**, a final rule that consolidated into a single submission the planning and application aspects of the

Department's Community Development Block Grant (CDBG), Emergency Shelter Grant (ESG), HOME Investment Partnerships (HOME), and Housing Opportunities for Persons with AIDS (HOPWA) programs. The purpose of this rule is to make an amendment to the deadline for submission of the Consolidated Plan in order to receive Community Development Block Grant funds.

The regulation requires jurisdictions to align the program years for the four formula programs and to submit the Consolidated Plan 45 days before the start of the program year instead of the 30 days previously recommended for submission of the CDBG Final Statement. The final date for submission of all Consolidated Plans was established as August 16. The final date previously established for submission of all CDBG final statements had been the first working day in September. To provide maximum flexibility during this transition period, HUD is amending the Consolidated Plan rule to permit the submission of the Consolidated Plan for Fiscal Year 1995 to be made not later than September 30, 1995.

#### Justification for Final Rulemaking

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking at 24 CFR part 10. However, part 10 provides that prior public procedure will be omitted if HUD determines that it is "impracticable, unnecessary, or contrary to the public interest" (24 CFR 10.1).

In this case, HUD finds that publishing this rule providing for a new consolidated plan deadline for FY 1995 for public comment would be impracticable and contrary to the public interest. Maximum flexibility in submitting consolidated plans during this first year of transition following publication of the final rule establishing the consolidated plan is in the public interest. The time necessary to allow for public comment would preclude the possibility of making the rule effective before the extended deadline date of September 30, 1995. It would be impracticable, therefore, to extend greater flexibility to grantees if a public comment period was provided before the rule takes effect.

#### Other Matters

##### *Executive Order 12866*

This final rule was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866 on Regulatory Planning and Review, issued by the President on September 30, 1993.