

E.O. 12612

This rule does not contain federalism implications warranting the preparation of a Federalism Assessment.

Regulatory Flexibility Act

As this rule is not subject to the requirement to provide prior notice and an opportunity for public comment pursuant to 5 U.S.C. section 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping duties, Business and industry, Cheese, Confidential business information, Countervailing duties, Investigations, Reporting and record keeping requirements.

Dated: August 30, 1999.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

For the reasons stated, 19 CFR part 351 is amended to read as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

Subpart A—Scope and Definitions

1. The authority citation for part 351 continues to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.*; and 19 U.S.C. 3538.

Subpart B—Antidumping and Countervailing Duty Procedures

2. Section 351.206(c)(2) is revised to read as follows:

§ 351.206 Critical circumstances.

* * * * *

- (c) * * *
- (2) The Secretary will issue the preliminary finding:
 - (i) Not later than the preliminary determination, if the allegation is submitted 20 days or more before the scheduled date of the preliminary determination; or
 - (ii) Within 30 days after the petitioner submits the allegation, if the allegation is submitted later than 20 days before the scheduled date of the preliminary determination; or
 - (iii) If, pursuant to paragraph (i) of this section, the period examined for purposes of determining whether critical circumstances exists is earlier than normal, the Secretary will issue the preliminary finding as early as possible after initiation of the investigation, but normally not less than 45 days after the

petition was filed. The Secretary will notify the Commission and publish in the **Federal Register** notice of the preliminary finding.

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[FR Doc. 99-23208 Filed 9-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Selamectin

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 Pfizer, Inc. The supplemental NADA provides for an additional indication for control of tick (*Dermacentor variabilis*) infestations in dogs.

EFFECTIVE DATE: September 8, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 141-152 that provides for topical veterinary prescription use of Revolution™ (selamectin) solution in dogs for the additional indication for control of tick (*D. variabilis*) infestations. The supplemental NADA is approved as of August 5, 1999, and the regulations are amended in 21 CFR 524.2098 in paragraphs (d)(1) and (d)(2) 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 21 CFR part 20 and 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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)(i)), this approval for nonfood-producing animals

qualifies for 3 years of marketing exclusivity beginning August 5, 1999, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.2098 [Amended]

2. Section 524.2098 *Selamectin* is amended in paragraph (d)(1) by removing the words "once a month" and in paragraph (d)(2) by revising the second sentence to read "Treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and control of tick (*Dermacentor variabilis*) infestations in dogs."

Dated: August 27, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99-23336 Filed 9-7-99; 8:45 am]

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FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2700

Procedural Rules

AGENCY: Federal Mine Safety and Health Review Commission.

ACTION: Final rule.