

Dated: September 1, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 99-23231 Filed 9-7-99; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket No. 9908128228-9228-01]

RIN 0625-AA56

Regulation Concerning Preliminary Critical Circumstances Findings

AGENCY: Import Administration, International Trade Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Department of Commerce (the "Department") is amending 19 CFR 351.206(c), which concerns preliminary findings of critical circumstances in antidumping and countervailing duty investigations. The critical circumstances provisions of the antidumping and countervailing duty laws and regulations ensure that the statutory remedies are not undermined by massive imports of dumped or subsidized merchandise following the filing of a petition. Normally, if an antidumping or countervailing duty order is issued, duties are assessed only on imports that enter the United States after the Department makes a preliminary determination of dumping or subsidization. However, where critical circumstances exist, duties are assessed retroactively on imports that enter up to 90 days prior to the preliminary determination. The amended regulation will ensure that the injurious effects of dumped or subsidized imports are remedied to the fullest extent provided by the law.

DATES: This rule is effective August 8, 1999.

FOR FURTHER INFORMATION CONTACT: Kathleen Hatfield, Office of Policy, Import Administration, U.S. Department of Commerce, at (202) 482-1930, or Marguerite Trossevin, Office of the Chief Counsel for Import Administration, U.S. Department of Commerce, at (202) 482-5593.

SUPPLEMENTARY INFORMATION:

Background

The U.S. antidumping and countervailing duty laws, as well as the relevant agreements of the World Trade Organization (WTO), contain "critical

circumstances" provisions to ensure that the statutory remedies for unfair trade practices are not undermined by massive imports of dumped or subsidized merchandise following the filing of a petition. Normally, if an antidumping or countervailing duty order is issued, duties are assessed only on imports that enter the United States after the Department makes its preliminary determination of dumping or subsidization, which normally takes place about four months after the filing of the petition. However, where critical circumstances exist, duties may be assessed retroactively on imports that enter up to 90 days prior to the preliminary determination.

Sections 703(e) (countervailing duties) and 733(e) (antidumping duties) of the Tariff Act of 1930, as amended (the Act), provide that, if a petitioner alleges critical circumstances, the Department of Commerce (the Department) "shall promptly (at any time after the initiation of the investigation under this subtitle)" determine whether there is reasonable cause to believe or suspect that critical circumstances exist. Recent experience highlights the importance of making preliminary critical circumstances findings as early as possible to ensure that import surges do not undermine the statutory remedies. Therefore, on October 15, 1998, the Department published Policy Bulletin 98/4, stating that the Department will issue preliminary findings on critical circumstances as soon as possible after initiation. The Department is codifying that policy to ensure that the injurious effects of dumped or subsidized imports are remedied to the fullest extent provided by the law.

Explanation of the Regulation

The antidumping and countervailing duty laws state that critical circumstances exist where there are massive imports over a relatively short period and, as appropriate, either (1) there is a history of dumping and material injury, or the importer knew or should have known that the merchandise was dumped and injury was likely as a result, or (2) there is a countervailable subsidy inconsistent with the WTO Subsidies Agreement. Pursuant to 19 CFR 351.206(i), for the purpose of determining the existence of an import surge, the Department normally will consider a "relatively short period" as the period beginning on the date the petition is filed and extending for at least the following three months. Imports during the post-petition period are compared to a period of comparable duration immediately

preceding the petition. If imports increased by at least 15 percent in the post-petition period, the Department deems such a surge to constitute "massive imports over a relatively short period."

Because necessary shipment data is often not immediately available when the normal comparison periods are used, it is virtually impossible to make a preliminary critical circumstances finding before Commerce's preliminary determination on the existence of dumping or subsidies. However, 19 CFR 351.206(i) further provides that, if the Department finds that, at some time prior to the filing of a petition, importers, exporters or producers had reason to believe that a proceeding was likely, the Department may consider a period of at least three months from that earlier time. In cases where earlier base periods are deemed appropriate, an earlier preliminary finding on critical circumstances may be possible because the necessary data may be available. However, because the International Trade Commission's (ITC) preliminary determination of injury may be important to the critical circumstances analysis, normally the earliest point at which a preliminary critical circumstances finding would be made is after the ITC preliminary determination, which is normally 45 days after the filing of the petition.

Accordingly, the Department is amending 19 CFR 351.206(c)(2) to provide that, where earlier base periods are used, the Department will issue preliminary critical circumstances findings as soon as possible after initiation of an investigation, but normally not less than 45 days after the filing of the petition.

Classification

Administrative Procedure Act

Pursuant to authority at 5 U.S.C. 553(b)(A), this rule of agency procedure is not subject to the requirement to provide prior notice and an opportunity for public comment. Further, because this rule of agency procedure is not substantive, it is not subject to the requirement in 5 U.S.C. 553(d) that its effective date be delayed 30 days.

E.O. 12866

This rule has been determined to be significant for purposes of Executive Order 12866.

Paperwork Reduction Act

This rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

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]

BILLING CODE 3510-DS-P

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)(iii)), 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.