Protection (CBP) Regulations (19 CFR part 111). Part 111 includes detailed rules regarding the licensing of, and granting of permits to, persons desiring to transact customs business as customs brokers, including the qualifications required of applicants and the procedures for applying for licenses and permits. Section 111.11 sets forth the basic requirements for a broker's license and, in paragraph (a)(4), provides that an applicant for an individual broker's license must attain a passing grade on a written examination taken within the 3-year period before submission of the license application prescribed under § 111.12.

Section 111.13 sets forth the requirements and procedures for the written examination for an individual broker's license. Paragraph (b) of § 111.13 concerns the date and place of the examination and, in the first sentence, provides that ''[w]ritten examinations will be given on the first Monday in April and October.''

On May 29, 2003, CBP published in the **Federal Register** (68 FR 31976) as T.D. 03–23 , an interim rule adding a provision that would allow CBP to publish a notice changing the date on which a semi-annual written examination for an individual broker's license will be held when the normal date conflicts with a holiday, religious observance, or other scheduled event. In the interim rule, CBP noted that the first Monday in October 2003, that is, October 6th, coincided with the observance of Yom Kippur, and CBP noted that the regulatory text quoted above did not provide for the adoption of alternative examination dates. In order to avoid conflicts with national holidays, religious observances, and other foreseeable events that could limit an individual's opportunity to take the broker's examination, T.D. 03–23 amended § 111.13(b) to provide CBP with some flexibility in those circumstances as regards the determination of the specific date on which an examination will be given. The interim rule requested comments, and those that were received are discussed below.

Discussion of Comments

Two commenters responded to the solicitation of public comment, and both requested that the regulation include a statement as to when the rescheduled examination will occur. Specifically, one commenter requested that the rescheduled examination date be no more than five business days (or one calendar week) later than the first Monday in April or the first Monday in October. The other commenter requested that we standardize the manner in which the rescheduled date will be determined, but did not request any specific time frame for the rescheduled date.

CBP believes that it is not necessary to include in the regulation a statement as to exactly when the rescheduled examination would occur. While CBP does not intend to schedule an examination later than one week after the first Monday in April or October, CBP believes that it would not be wise to standardize the rescheduled date(s) because CBP contracts the administration of the examinations to the Office of Personnel Management (OPM). Standardization as to when an examination would be rescheduled could unduly constrain CBP and OPM to what may become ill-timed or unavailable dates.

Conclusion

After analysis of the comments and further review of the matter, CBP has determined to adopt as a final rule, with no changes, the interim rule published in the **Federal Register** (68 FR 31976) on May 29, 2003, as T.D. 03–23.

Signing Authority

This final rule is being issued in accordance with 19 CFR 0.1(b)(1) of the CBP Regulations.

Inapplicability of Notice and Delayed Effective Date Requirements and the Regulatory Flexibility Act

Because this regulation finalizes an interim rule already in effect that provides a benefit to prospective applicants for individual customs broker licenses and imposes no new regulatory burden or obligation on any member of the general public, CBP finds that, pursuant to the provisions of 5 U.S.C. 553(d)(1) and (3), there is good cause for dispensing with a delayed effective date. Because no notice of proposed rulemaking is required for interim regulations, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) do not impose restrictions on the publication of this regulation.

Executive Order 12866

This document does not meet the criteria for a ''significant regulatory action'' as specified in E.O. 12866.

Drafting Information

The principal author of this document was Dwayne S. Rawlings, Office of Regulations and Rulings, Bureau of Customs and Border Protection.

List of Subjects in 19 CFR Part 111

Administrative practice and procedure, Brokers, Customs duties and inspection, Imports, Licensing, Reporting and recordkeeping requirements.

Amendment to the Regulations

■ For the reasons set forth above, the interim rule amending § 111.13 of Title 19 of the Code of Federal Regulations (19 CFR part 111.13), which was published in the **Federal Register** (68 FR 31976) on May 29, 2003, as T.D. 03–23, is adopted as a final rule without change.

Dated: August 24, 2004.

Robert C. Bonner,

Commissioner, Customs and Border Protection.

[FR Doc. 04–19664 Filed 8–27–04; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Cefpodoxime Proxetil Tablets

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 new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The NADA provides for veterinary prescription use of cefpodoxime proxetil tablets in dogs for treatment of skin infections (wounds and abscesses) caused by susceptible strains of certain bacteria.

DATES: This rule is effective August 30, 2004.

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, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed NADA 141–232 for use of SIMPLICEF (cefpodoxime proxetil) Tablets. The NADA provides for veterinary prescription use of cefpodoxime proxetil tablets in dogs for treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *S. aureus*, *Streptococcus canis* (group G, β-

hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*. The NADA is approved as of July 22, 2004, and the regulations are amended in part 520 (21 CFR part 520) by adding § 520.370 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 22, 2004.

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

This 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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Section 520.370 is added to read as follows:

§ 520.370 Cefpodoxime tablets.

(a) *Specifications*. Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

(b) *Sponsors*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 5 to 10 mg per kilogram (2.3 to 4.5 mg per pound) body weight daily for 5 to 7 days, or for 2 to 3 days beyond the cessation of clinical signs, up to a maximum of 28 days.

(2) *Indications for use*. For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *S. aureus*, *Streptococcus canis* (group G, β-hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 17, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–19654 Filed 8–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Spectinomycin Dihydrochloride Oral 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 Cross Vetpharm Group Ltd. The ANADA provides for the oral use of spectinomycin dihydrochloride pentahydrate oral solution in pigs under 4 weeks of age for the treatment and control of infectious bacterial enteritis.

DATES: This rule is effective August 30, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–364 that provides for oral use of SPECMED (spectinomycin dihydrochloride pentahydrate) Scour-Chek in pigs under 4 weeks of age for the treatment and control of infectious bacterial enteritis (white scours) associated with *Escherichia coli*. Cross Vetpharm Group Ltd.'s SPECMED Scour-Chek is approved as a generic copy of Phoenix Scientific, Inc.'s SPECTAM Scour Halt, approved under NADA 033–157. The ANADA is approved as of July 29, 2004, and the regulations are amended by removing 21 CFR 520.2122 and by adding 21 CFR 520.2123c to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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.

The agency has determined under 21 CFR 25.33(a)(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.

This 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 Subject in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.2122 [Removed]

■ 2. Section 520.2122 is removed.

■ 3. Section 520.2123c is added to read as follows:

§ 520.2123c Spectinomycin dihydrochloride pentahydrate solution.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) spectinomycin activity.

(b) *Sponsors*. See Nos. 000856, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount*. Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.