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.

(2) *Indications for use.* For the treatment and control of infectious bacterial enteritis (white scours) associated with *E. coli* in pigs under 4 weeks of age.

(3) *Limitations.* Do not administer to pigs over 15 lb of body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

Dated: August 17, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–19655 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 558

New Animal Drugs For Use in Animal Feeds; Decoquinate

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 Alpharma Inc. The supplemental NADA provides for the use of single-ingredient decoquinate and monensin Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at a broader range of concentrations.

DATES: This rule is effective August 30, 2004.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *janis.messenheimer@fda.gov*.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 141–148 for use of DECCOX (decoquinate) and RUMENSIN (monensin sodium) Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at the broader range of concentrations. The supplemental application is approved as of July 30, 2004, and the regulations are amended in 21 CFR 558.195 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 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 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.195 [Amended]

■ 2. Section 558.195 *Decoquinate* is amended in paragraph (e)(2)(iv) in the table in the ''Decoquinate in grams/ton'' column by removing ''13.6 to 27.2'' and by adding in its place ''12.9 to 90.8''; and in the ''Limitations'' column after the fourth sentence by adding ''Do not feed to lactating dairy cattle.''

Dated: August 18, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–19696 Filed 8–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9157]

RIN 1545–AW33

Guidance Regarding the Treatment of Certain Contingent Payment Debt Instruments With One or More Payments That Are Denominated in, or Determined by Reference to, a Nonfunctional Currency

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations regarding the treatment of contingent payment debt instruments for which one or more payments are denominated in, or determined by reference to, a currency other than the taxpayer's functional currency. These regulations are necessary because current regulations do not provide guidance concerning the tax treatment of such instruments. The regulations affect issuers and holders of such instruments.

DATES: *Effective Date:* These regulations are effective August 30, 2004.

Applicability date: These regulations apply to debt instruments issued on or after October 29, 2004.

FOR FURTHER INFORMATION CONTACT: Milton Cahn, (202) 622–3860 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1831. Responses to these collections of information are mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

The estimated annual burden per [respondent/recordkeeper] varies from 48 minutes to 1 hour 12 minutes, depending on individual circumstances, with an estimated average of 1 hour.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS