From	To	Changeover points	
		Distance	From
§ 95.8003 VOR Federal Airway Changeover Points Airway Segment V–16 is Amended to Read in Part			
Texarkana, AR VORTAC	Pine Bluff, AR VOR/DME	62	Texarkana
V–124 is Amended to Delete			
Hot Springs, AR VOR/DME			

[FR Doc. 98–7027 Filed 3–17–98; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Amoxicillin Trihydrate and Clavulanate Potassium

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 two supplemental new animal drug applications (NADA's) filed by Pfizer, Inc. The supplemental NADA's provide for oral use amoxicillin trihydrate and clavulanate potassium tablets and suspension for treatment of dogs for periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

EFFECTIVE DATE: March 18, 1998.

FOR FURTHER INFORMATION CONTACT: Mary E. Reese, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20857, 301–594–1617.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA's 55–099 and 55–101 that provide for oral use of amoxicillin trihydrate and clavulanate potassium tablets and suspension for treatment of dogs for periodontal infections due to susceptible strains of aerobic and anaerobic bacteria. The products are limited to use by or on the order of a licensed veterinarian. The supplemental NADA's are approved as of December 23, 1997, and the regulations are amended in 21 CFR 520.88g and 520.88h 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 the supplemental applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, from 9 a.m. to 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)), these approvals for nonfood-producing animals qualify for 3 years of marketing exclusivity beginning December 23, 1997, because the supplemental applications contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for approval of the applications and conducted or sponsored by the applicant. Three years of marketing exclusivity applies only to use of Clavamox® tablets and suspension in dogs for treatment of periodontal infections caused by susceptible strains of aerobic and anaerobic bacteria.

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

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 520.88g is amended in paragraph (c)(1)(ii) by adding a new sentence at the end of the paragraph to read as follows:

§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.

* * * * *

(c) * * *

(1) * * *

(ii) * * * Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

* * * * *

3. Section 520.88h is amended in paragraph (c)(1)(ii) by adding a new sentence at the end of the paragraph to read as follows:

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

* * * * *

(c) * * *

(1) * * *

(ii) * * * Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

* * * * *

Dated: February 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–6907 Filed 3–17–98; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Desoxycorticosterone Pivalate

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 Novartis Animal Health US, Inc. The NADA provides for use of desoxycorticosterone pivalate as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

EFFECTIVE DATE: March 18, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 26402, Greensboro, NC 27404–6402, is the sponsor of NADA 141–029 that provides for the use of Percorten™-V (desoxycorticosterone pivalate) as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of January 12, 1998, and the regulations are amended by adding new 21 CFR 522.535 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 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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.

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 for nonfood-producing animals qualifies for 5 years of marketing exclusivity beginning January 12, 1998, because no active ingredient of the drug (including any salt or ester of the active ingredient) has been approved in any other application.

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: 21 U.S.C. 360b.

2. New § 522.535 is added to read as follows:

§ 522.535 Desoxycorticosterone pivalate.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 25 milligrams of desoxycorticosterone pivalate.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(ii) *Indications for use.* For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) *Limitations.* For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: February 6, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–6911 Filed 3–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Colistimethate Sterile Powder

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 Alpharma Inc. The NADA provides for subcutaneous use of colistimethate sodium powder, reconstituted in aqueous solution, in the neck of 1- to 3-day-old chickens.

EFFECTIVE DATE: March 18, 1998.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–069 that provides for use of First Guard™ Sterile Powder (colistimethate sodium), reconstituted in sterile saline or sterile water for injection, for subcutaneous injection in the neck of 1- to 3-day-old chickens for control of early mortality associated with *Escherichia coli* organisms susceptible to colistin. The drug is restricted to use by or on the order of a licensed veterinarian. The NADA is approved as of January 13, 1998, and the regulations are amended by adding new § 522.468 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulations are amended by adding new § 556.167 to reflect that a tolerance for residues of colistimethate in edible chicken tissues is not required. The drug is a therapeutic product administered to 1- to 3-day-old chickens at the equivalent of 0.2 milligrams of colistin activity per chicken. At 28 days post-treatment, the earliest possible time broiler chickens would be considered marketable, total residues were calculated to be at least 36 times below the safe concentration level.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 for food-producing animals qualifies for 5 years of marketing exclusivity beginning January 13, 1998, because no active ingredient of the drug (including any ester or salt thereof) has been previously approved in any other application filed under section 512(b)(1) of the act.

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