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.

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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.