DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
21 CFR Part 5  
Delegations of Authority and Organization; Office of the Commissioner  

AGENCY: Food and Drug Administration, HHS.  

ACTION: Final rule.  

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority from the Commissioner of Food and Drugs to other officers of FDA in order to give the Associate Commissioner for Policy Coordination, Office of Policy, authority to issue Federal Register notices and proposed and final regulations for FDA. This action is being taken in order to hasten the process of issuing such notices and proposed and final regulations. This authority may not be further redelegated at this time.  

EFFECTIVE DATE: January 26, 1996.  

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management, Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fisher's Lane, Rockville, MD 20857, 301-443-4976.  

SUPPLEMENTARY INFORMATION: FDA is amending the regulations in §5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration. 

Dated: January 19, 1996.  
William B. Schultz,  
Deputy Commissioner for Policy.  

[FR Doc. 96-1322 Filed 1-25-96; 8:45 am]  
BILLING CODE 4160-01-F  

21 CFR Part 558  
New Animal Drugs For Use In Animal Feeds; Chlortetracycline, Sulfaflaxazole, Penicillin  

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 Fermenta Animal Health Co. The supplement provides for use of fixed combination Type A medicated articles containing chlortetracycline, sulfathiazole, and penicillin in making Type B and C medicated swine feeds for swine from 10 pounds to 6 weeks post-weaning.

EFFECTIVE DATE: January 26, 1996.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855, 301–594–1607.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153, filed a supplement to NADA 39–077 CSP (200) 250 (20 grams (g) of chlortetracycline (as the hydrochloride), 20 g of sulfathiazole, and 10 g of penicillin (as penicillin procaine), per pound) and CSP 500 (40 g of chlortetracycline (as the hydrochloride), 40 g of sulfathiazole, and 20 g of penicillin (as penicillin procaine), per pound). The NADA provides for use of fixed combination Type A medicated articles to make Type B and C medicated swine feeds for prestarter, starter, grower, and finisher rations. The supplement provides for prestarter and starter rations to be given to swine from 10 pounds of body weight to 6 weeks post-weaning for reduction of incidence of cervical abscesses, treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by Salmonella choleraesuis and vibrionic dysentery), maintenance of weight gains in the presence of atrophic rhinitis, increased rate of weight gain and improved feed efficiency. Swine 6 to 16 weeks of age are given Type B and Type C medicated feeds as approved NADA 39–077 and in § 558.155.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, 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 supplemental approval does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re-delegated 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:


2. Section 558.155 is amended by revising the section heading and paragraphs (d)(2) and (d)(3) to read as follows:

§ 558.155 Chlortetracycline, sulfathiazole, penicillin.

(d) * * *

(2) Indications for use. For reduction of incidence of cervical abscesses. Treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by Salmonella choleraesuis and vibrionic dysentery). Maintenance of weight gains in the presence of atrophic rhinitis. Swine 10 pounds of body weight to 6 weeks post-weaning; Increased rate of weight gain and improved feed efficiency. Swine 6 to 16 weeks post-weaning; Increased rate of weight gain.

(3) Limitations. For swine raised in confinement (dry-lot) or on limited pasture. Feed as sole ration. Withdraw 7 days prior to slaughter.

Dated: January 3, 1996.

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

[FR Doc. 96–1323 Filed 1–25–96; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD02–95–003]

RIN 2115–AE84

Regulated Navigation Area; Ohio River Mile 466.0 to Mile 473.0

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a regulated navigation area on the Ohio River in the Cincinnati, OH area. The rule is needed to control vessel traffic while transiting downbound at night during high water conditions in the regulated area. The rule will restrict commercial navigation in the regulated area for the safety of vessel traffic and the protection of life and property along the river.

EFFECTIVE DATE: This rule is effective February 26, 1996.

ADDRESSES: The Commanding Officer, U.S. Coast Guard Marine Safety Office, Louisville, KY, maintains the public docket for this rule. The documents and