List of Subjects in 19 CFR Part 4

Customs duties and inspection, Reporting and recordkeeping requirements, Vessels.

Amendments to the Regulations

Part 4, Customs Regulations (19 CFR Part 4), is amended as set forth below.

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The general authority citation for Part 4, Customs Regulations (19 CFR Part 4) and specific authority citation for section 4.8 continue, and the specific authority citation for section 4.30 is revised, to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624; 46 U.S.C. App. 3, 91;

* * * * *

Section 4.8 also issued under 19 U.S.C. 1448, 1486;

* * * * *

Section 4.30 also issued under 19 U.S.C. 288, 1446, 1448, 1450–1454, 1490;

* * * * *

2. Section 4.8 is revised to read as follows:

§ 4.8 Preliminary entry.

Preliminary entry allows a U.S. or foreign vessel arriving under circumstances which require it to formally enter, to discharge cargo, passengers, or baggage prior to making formal entry. The granting of preliminary entry may be accomplished electronically pursuant to an authorized electronic data interchange system, or by other means of communication approved by the Customs Service. Preliminary entry must be made in compliance with § 4.30 of this part. The granting of preliminary vessel entry by the Customs Service may be conditioned upon the presentation of a completed Customs Form 1300 (Master's Certificate on Preliminary Entry) to Customs during discretionary vessel boarding, or upon the filing with Customs of a Customs Form 1300 or its equivalent by electronic or other means in instances where vessels are not boarded.

3. Section 4.30 (a) is amended by removing the period at the end and adding the words ''or electronically pursuant to an authorized electronic data interchange system or other means of communication approved by the Customs Service.''

4. Section 4.30(b) is amended by adding after the phrase ''Customs Form 3171,'' the words '' or electronically pursuant to an authorized electronic data interchange system or other means of communication approved by the Customs Service,''.

George J. Weise,

Commissioner of Customs.

Approved: November 24, 1995.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–1327 Filed 1–25–96; 8:45 am]

BILLING CODE 4820–02–P

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 redelegations 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 Fishers 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* (21 CFR 5.20) in order to add the title of Associate Commissioner for Policy Coordination to those authorized 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.

Further redelegation of these authorities is not authorized at this time. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701–1706; 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.20 is amended by revising paragraph (f)(1) to read as follows:

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

* * * * *

(f)(1) The Deputy Commissioner for Policy and the Associate Commissioner for Policy Coordination are authorized to perform any of the functions of the Commissioner of Food and Drugs with respect to the issuance of Federal Register notices and proposed and final regulations 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, Sulfathiazole, 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 (HFV–128), Food and Drug Administration, 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™ 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 postweaning 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 atropic rhinitis, increased rate of weight gain and improved feed efficiency. The supplement is approved as of January 26, 1996, and the regulations are amended in § 558.155 (21 CFR 558.155) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the agency is revising the section heading for § 558.155 to reflect the active ingredients as on the label, i.e., that the product is known as chlortetracycline with sulfathiazole and penicillin, not as chlortetracycline hydrochloride with procaine penicillin and sulfathiazole. The approvals paragraph does specify the salts and esters approved for use.

In § 558.155(d) the feed consumption table is removed. The performance or therapeutic claims of the product are based on *ad libitum* consumption and not the minimum desired daily feed intake consumption values reported in the table. This, together with changes in weaning weights, renders the table obsolete. Also, the indications for use are editorially revised to clarify the indications for each feeding group.

The product, chlortetracycline, sulfathiazole, and penicillin, in combination in a Type A medicated article, is a new animal drug used to make Type B and Type C medicated feeds. As provided in § 558.4(b), the combination drug product is a Category II drug because it requires a withdrawal period at its lowest continuous use level. Therefore, it requires an approved Form FDA 1900 for making Type B or Type C medicated feeds as in 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 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: Sec. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

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