7. Anonymous, ''U. S. Sun Crop: Potential Still not Realized,'' *Journal of the American Oil Chemists' Society*, 63:1218–1224, 1986.

8. Faulkner, R. W., ''Cocoa Butter Equivalents are Truly Specialty Vegetable Fats,'' *The Manufacturing Confectioner*, pp. 56–61, 1981.

9. Memorandum from M. DiNovi, FDA to L. Lin, FDA, November 2, 1988.

10. Feuge, R. O. et al., ''Cocoa Butter-Like Fats from Domestic Oils,'' *Journal of the American Oil Chemists' Society*, 35:194–199, 1958.

11. Lehninger, A. L., *Principles of Biochemistry*, Worth Publishers, Inc., New York, NY, 1982.

12. Memorandum from J. C. Griffiths, FDA to L. Lin, FDA, July 14, 1989.

13. Shimoda, T. et al., ''Safety Studies of a Transesterified Fat Produced by an Immobilized Lipase: I. Acute Oral Toxicity Study in Rats,'' *Journal of the American College of Toxicology*, 13 (Suppl. 1):10–18, 1994.

14. Shimoda, T. et al., ''Safety Studies of a Transesterified Fat Produced by an Immobilized Lipase: II. Subchronic Oral Toxicity and Recovery Studies in Rats,'' *Journal of the American College of Toxicology*, 13 (Suppl. 1):19–37, 1994.

15. Shimoda, T. et al., ''Safety Studies of a Transesterified Fat Produced by an Immobilized Lipase: III. Bacterial Reversion Test,'' *Journal of the American College of Toxicology*, 13 (Suppl. 1):38–45, 1994.

16. MacRae, A. R., ''Lipase-Catalysed Interesterification of Oils and Fats,'' *Journal of the American Oil Chemists' Society*, 60:291–294, 1983.

List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1259 is amended by revising the section heading and paragraph (a) to read as follows:

§ 184.1259 Cocoa butter substitute.

(a) The common or usual name for the triglyceride 1-palmitoyl-2-oleoyl-3-stearin is ''cocoa butter substitute primarily from palm oil.'' The common or usual name for the triglyceride 1-3-distearoyl-2-olein is ''cocoa butter substitute primarily from high-oleic safflower or sunflower oil.''

(1) The ingredient 1-palmitoyl-2-oleoyl-3-stearin is manufactured by:

(i) Directed esterification of fully saturated 1,3-diglycerides (derived from palm oil) with the anhydride of food-grade oleic acid in the presence of the catalyst trifluoromethane sulfonic acid (§ 173.395 of this chapter), or

(ii) By interesterification of partially saturated 1,2,3-triglycerides (derived from palm oil) with ethyl stearate in the presence of a suitable lipase enzyme preparation that is either generally recognized as safe (GRAS) or has food additive approval for such use.

(2) The ingredient 1-3-distearoyl-2-olein is manufactured by interesterification of partially unsaturated 1,2,3-triglycerides (derived from high-oleic safflower or sunflower oil) with ethyl stearate or stearic acid in the presence of a suitable lipase enzyme preparation that is either GRAS or has food additive approval for such use.

* * * * *

Dated: June 13, 1996.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–17542 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 abbreviated new animal drug application (ANADA) filed by Boehringer Ingelheim Animal Health, Inc. The supplemental ANADA provides for the subcutaneous use of oxytetracycline injection in cattle for treatment of diseases caused by oxytetracycline susceptible organisms.

EFFECTIVE DATE: July 10, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506, has filed supplemental ANADA 200–008, which provides for subcutaneous use of oxytetracycline injection in addition to the approved intravenous and intramuscular use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresi*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. The product is also approved for intramuscular use in swine.

Boehringer Ingelheim's supplemental ANADA 200–008 for subcutaneous use of oxytetracycline injection (OXY–TET 200/BIO–MYCIN 200) in cattle is approved as of May 22, 1996, and the regulations are amended in 21 CFR 522.1660 (c)(1)(iii) 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 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, 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 25.24(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 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (c)(1)(iii) by revising the first sentence to read ''Administer intramuscularly, intravenously, or subcutaneously at 3 to 5 milligrams level, intramuscularly or subcutaneously at 9 milligrams level.'' * * *

Dated: June 25, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–17541 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

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 Hoffmann-La Roche, Inc. The supplemental NADA provides for use of a free-choice, mineral, Type C cattle feed containing chlortetracycline (CTC) for grazing beef cattle weighing over 700 pounds (lb) for control of active anaplasmosis infections.

EFFECTIVE DATE: July 10, 1996.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110, filed a supplement to NADA 48–761, Aureomycin® (chlortetracycline) mineral, Type C cattle feed containing 4 grams CTC per lb. The supplement provides for free-choice feeding to grazing beef cattle weighing over 700 lb at 0.0125 to 0.05 lb of Type C feed per 100 lb of body weight per day (0.5 to 2.0 milligrams (mg) CTC per lb of body weight per day) for control of active infections of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline. The supplement is approved as of July 10, 1996, and the regulations are amended in 21 CFR 558.128(c)(4) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

With approval of this supplement, cattle may be fed 0.5 to 2.0 mg CTC per head per day. To provide for safe use at the upper limit, a withdrawal time of 4 days prior to slaughter is provided.

Use of Type A medicated articles to make free-choice CTC Type C medicated feeds requires an approved Form FDA 1900 as in 21 CFR 510.455.

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, 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning July 10, 1996, because the supplemental application contains 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 3 years of marketing exclusivity applies only to the new claim for which the supplement was approved.

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 in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.128 [Amended]

2. Section 558.128 *Chlortetracycline* is amended in paragraph (c)(4) by removing the phrase ''daily minimum intake of 0.5 milligram of chlortetracycline per pound of body weight to aid in the prevention of anaplasmosis'' and adding in its place ''daily intake of 0.5 to 2.0 milligrams of chlortetracycline per pound of body weight to aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; discontinue use 4 days prior to slaughter''.

Dated: May 31, 1996.

Robert C. Livingston,

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

[FR Doc. 96–17315 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy has determined that USS KINGFISHER (MHC 56) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special functions as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: June 25, 1996.

FOR FURTHER INFORMATION CONTACT: Captain R.R. Pixa, JAGC, U.S. Navy Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, Virginia, 22332–2400, Telephone Number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy, under