grub, lice, and mange mite infections, to control infection and to protect from reinfection with *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment, and *Haemonchus placei, Trichostrongylus axei, Cooperia punctata, C. oncophora,* and *Oesophagostomum radiatum* for 14 days after treatment. Also, NADA 140–833 provides for treatment and control of liver flukes. Merial Ltd. filed supplements to both NADA's that amend their use to provide for control of infection and protection from reinfection of *Dictyocaulus viviparus* for 28 days after treatment. The supplements are approved as of April 1, 1999, and the regulations are amended in 21 CFR 522.1192(d)(2)(ii) and 522.1193(d)(2) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has revised the tolerances for residues of ivermectin to establish an acceptable daily intake and a swine muscle tolerance (63 FR 54352, October 9, 1998). At this time, FDA further amends the ivermectin residue tolerances in 21 CFR 556.344 to establish a cattle muscle tolerance.

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 these applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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)), these supplemental approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning April 1, 1999, because the supplements contain substantial evidence of effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplements and conducted or sponsored by the applicant. Exclusivity applies only to the additional indication for persistent effectiveness.

FDA has determined under 21 CFR 25.33(a)(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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are 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.

§ 522.1192 [Amended]

2. Section 522.1192 *Ivermectin injection* is amended in paragraph (d)(2)(ii) in the last sentence by removing ''*D. viparus* and'' and adding in its place ''*D. viviparus* for 28 days after treatment,''.

3. Section 522.1193 is amended in paragraph (d)(2) by revising the last sentence to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

* * * * *

(d) * * *

(2) * * * It is also used to control infections of *D. viviparus* for 28 days afer treatment, *O. ostertagi* for 21 days after treatment, and *H. placei, T. axei, C. punctata, C. oncophora, and O. radiatum* for 14 days after treatment.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

4. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

5. Section 556.344 is amended by adding paragraph (b)(2)(ii) to read as follows:

§ 556.344 Ivermectin.

* * * * *

(b) * * *

(2) * * *

(ii) *Cattle*. 10 parts per billion.

Dated: May 3, 1999.

Margaret Ann Miller,

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

[FR Doc. 99–12286 Filed 5–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Sulfadimethoxine with Ormetoprim

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 Roche Vitamins, Inc. The supplemental NADA provides for use of sulfadimethoxine/ormetoprim type A medicated articles to make type C medicated chukar partridge feeds used for the prevention of coccidiosis. Also, FDA is amending the regulations to reflect tolerances for residues of sulfadimethoxine and for ormetoprim in edible chukar partridge tissues.

EFFECTIVE DATE: May 17, 1999.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298, filed supplemental NADA 40–209 that provides for use of Rofenaid® 40 (113.5 grams per pound (g/lb) (25 percent) sulfadimethoxine with 68.1 g/lb (15 percent) ormetoprim) type A medicated articles to make type C chukar partridge feeds containing 113.5 grams per ton (g/t) sulfadimethoxine and 68.1 g/t ormetoprim. The type C chukar partridge feeds are fed continuously to young birds up to 8 weeks of age for the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*. The supplemental NADA is approved as of April 1, 1999. The regulations are amended in 21 CFR 558.575 to redesignate paragraph (c) as paragraph (d), to reserve paragraph (c), to amend paragraph (a) to reflect the redesignation and to reflect the approval, and to add paragraph (d)(7) to further reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, tolerances are established for sulfadimethoxine and for ormetoprim residues in edible chukar partridge tissues. The regulations are amended in 21 CFR 556.490 and 556.640, accordingly.

Approval of this supplement is based on data and information in Public Master File (PMF) 5157. The notice of availability of a summary of the data and information in PMF 5157 and of permission to use it to support approval of a NADA or supplemental NADA was published in the **Federal Register** of July 19, 1996 (61 FR 37753).

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(d)(4) 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

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.490 is revised to read as follows:

§ 556.490 Ormetoprim.

(a) [Reserved]

(b) *Tolerances*. A tolerance of 0.1 part per million (ppm) is established for negligible residues of ormetoprim in uncooked edible tissues of chickens, turkeys, ducks, salmonids, catfish, and chukar partridges.

3. Section 556.640 is revised to read as follows:

§ 556.640 Sulfadimethoxine.

(a) [Reserved]

(b) *Tolerances*. (1) A tolerance of 0.1 part per million (ppm) is established for negligible residues of sulfadimethoxine in uncooked edible tissues of chickens, turkeys, cattle, ducks, salmonids, catfish, and chukar partridges.

(2) A tolerance of 0.01 ppm is established for negligible residues of sulfadimethoxine in milk.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

4. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

5. Section 558.575 is amended by revising paragraph (a), redesignating paragraph (c) as paragraph (d), reserving paragraph (c), and adding paragraph (d)(7) to read as follows:

§ 558.575 Sulfadimethoxine, ormetoprim.

(a) *Approvals*. Type A medicated articles to sponsors as identified in § 510.600(c) of this chapter for uses as in paragraph (d) of this section as follows:

(1) 25 percent sufadimethoxine and 15 percent ormetoprim to 000004 for use for poultry as in paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(7) of this section.

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim to 000004 for use for fish as in paragraphs (d)(5) and (d)(6) of this section.

* * * * *

(c) [Reserved]

(d) * * *

(7) *Chukar partridges*—(i) *Amount per ton*. Sulfadimethoxine 113.5 grams (0.0125 percent) plus ormetoprim 68.1 grams (0.0075 percent).

(ii) *Indications for use*. For prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*.

(iii) *Limitations*. Feed continuously to young birds up to 8 weeks of age as sole ration.

Dated: April 30, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–12285 Filed 5–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 151

[USCG 1998–3423]

RIN 2115–AF55

Implementation of the National Invasive Species Act of 1996 (NISA)

AGENCY: Coast Guard, DOT.

ACTION: Interim rule with request for comments.

SUMMARY: To comply with the National Invasive Species Act of 1996 (NISA), the Coast Guard establishes both regulations and voluntary guidelines to control the invasion of aquatic nuisance species (ANS). Ballast water from ships is one of the largest pathways for the intercontinental introduction and spread of ANS. This rule amends existing regulations for the Great Lakes ecosystem, establishes voluntary ballast water management guidelines for all other waters of the United States, and establishes mandatory reporting for nearly all vessels entering waters of the United States.

DATES: This interim rule is effective July 1, 1999. Comments and related material must reach the Docket Management Facility on or before July 16, 1999. Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before July 16, 1999.

ADDRESSES: You may submit your comments and material by mail, hand delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one of the following methods to help us avoid confusion in the public docket:

(1) By mail to the Docket Management Facility (USCG–1998–3423), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By hand delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at http://dms.dot.gov.

You may also mail comments on collection of information to the Office of Information and Regulatory Affairs,