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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: (*Insert date of publication in the Federal Register.*)

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:

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 sulfadimethoxine 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.

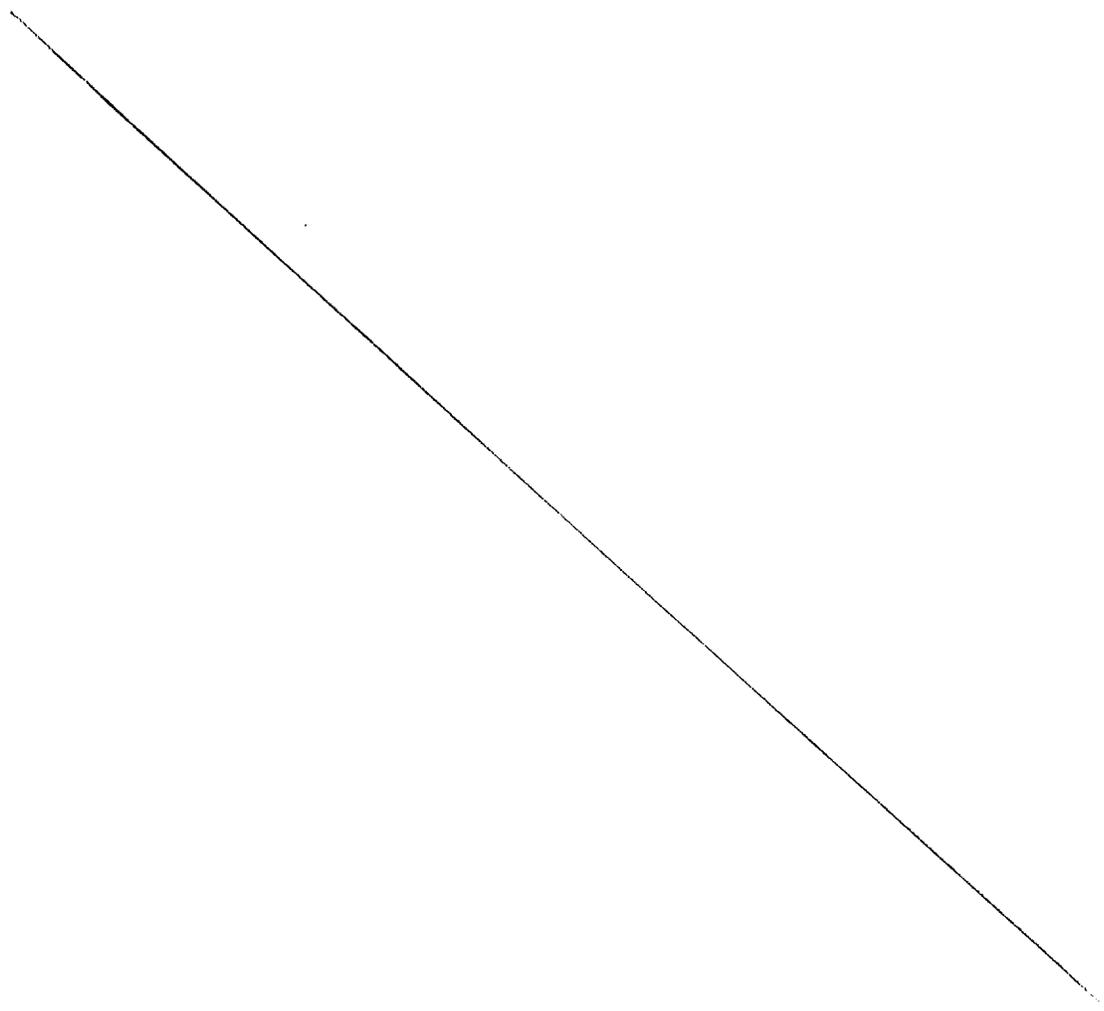
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(b) * * * * *

(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).

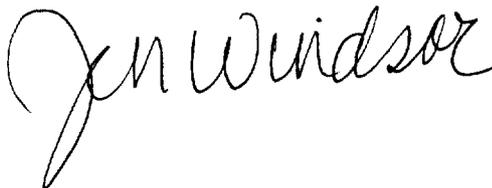


(ii) *Indications for use.* For prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*.

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

Dated: 4/30/99
April 30, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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