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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; Lasalocid

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 a lower concentration lasalocid Type A medicated article to make a Type C rabbit feed used for prevention of coccidiosis and to provide for a tolerance for drug residues in rabbits.

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

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-7575.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298, filed supplemental NADA 96-298 that provides for use of **Bovatec®** (15 percent **lasalocid**) in addition to previously approved use of **Avatec®** (20 percent **lasalocid**) Type A medicated articles to make 113 grams per ton **lasalocid** Type C rabbit feeds used for prevention of coccidiosis caused by *Eimeria stiedae*. The supplemental NADA is approved as of February 5, 1999, and the regulations are amended in 21 CFR 558.311(b)(4) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

At this time, the human food safety data originally submitted in public master file 5042 for use of lasalocid in rabbits was reevaluated and a tolerance for drug residues in edible rabbit tissues is established in 21 CFR 556.347. Also, that section is revised to reflect current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and **514.110**, a summary of safety and effectiveness data and information submitted to support approval of this supplemental 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.

The agency has determined under 21 CFR 25.33(a)(1) 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 authority delegated to the Commissioner of Food and Drugs and redelegate 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 556.347 is revised to read as follows:

§ 556.347 **Lasalocid.**

(a) [Reserved]

(b) Tolerances—(1) *Chickens*. A tolerance is established for **lasalocid** residues of 0.3 part per million (ppm) parent **lasalocid** (marker residue) in skin with adhering fat (target tissue).

(2) *Cattle*. A tolerance is established for **lasalocid** residues of 0.7 ppm parent **lasalocid** (marker residue) in liver (target tissue).

(3) *Sheep*. A tolerance for residues of **lasalocid** is not needed.

(4) *Rabbits*. A tolerance is established for **lasalocid** residues of 0.7 ppm parent **lasalocid** (marker residue) in liver (target tissue).

PART 558-NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

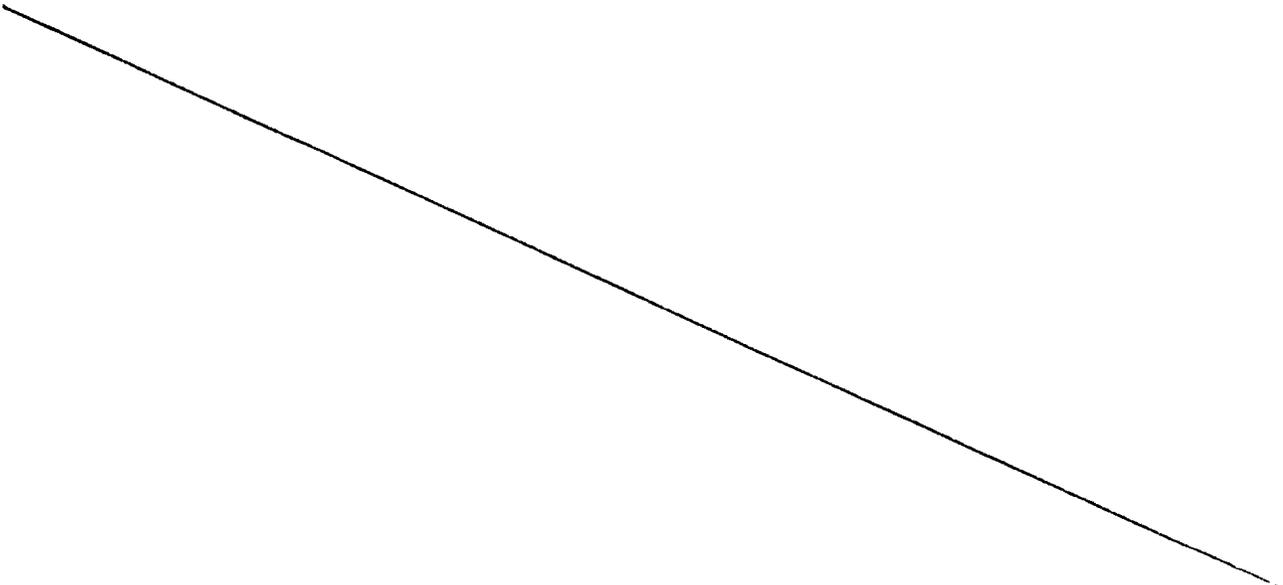
Authority: 21 U.S.C. 360b,371.

4. Section 558.311 is amended by revising paragraph (b)(4) to read as follows:

§ 558.311 **Lasalocid.**

* * * * *

(b) * * *



(4) 15 percent activity to No. 063238 for use in Type C rabbit feeds as in paragraph (e)(1) (xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2) and (e)(3) of this section.

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Dated: Feb -23. 1999

February 23, 1999



Andrew J. Beaulieu
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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