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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Display Date 1-8-04
Publication Date 1-9-04
Certifier A. Corbin

New Animal Drugs; 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 new animal drug application (NADA) filed by Ridley Block Operations, Inc. The NADA provides for the use of a lasalocid Type A medicated article to manufacture free-choice, Type C medicated protein feed blocks used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Ridley Block Operations, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500, filed NADA 141-187 that provides for use of BOVATEC 68 (lasalocid) Type A medicated article to manufacture CRYSTALYX IONO-LYX, free-choice Type C medicated protein feed blocks containing 300 grams lasalocid per ton. The free-choice medicated feed protein block is used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). The NADA is approved as of December 12, 2003, and the regulations are amended

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NADA 141-187

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in 21 CFR 558.311 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Ridley Block Operations, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning.

The agency has determined under 21 CFR 25.33(a)(6) 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.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for “Ridley Block Operations Inc.” and in the table in paragraph (c)(2) by numerically adding a new entry for “068287” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500.	068287

(2) * * *

Drug labeler code	Firm name and address
068287	Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500

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 adding paragraphs (b)(9) and (e)(1)(xix) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(9) 15 percent activity to No. 068287 for use in free-choice protein blocks for cattle as in paragraphs (e)(1)(xix) of this section.

* * * * *

(e) * * *

(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xix) 300		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain.	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	068287

* * * * *

Dated: 12/29/03

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December 29, 2003.



Linda Tollefson,
Deputy Director,
Center for Veterinary Medicine.

> [FR Doc. 03-⁴????? Filed ??-??-03⁴; 8:45 am]

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