4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Argent Laboratories; Formalin; Tricaine Methanesulfonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of two new animal drug applications (NADAs) held by Argent Laboratories. Withdrawal of approval of these NADAs was at the sponsor's request because the products are no longer manufactured or marketed.

DATES: This final rule is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843 david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052 has requested that FDA withdraw approval of the following two NADAs because the products are no longer manufactured or marketed: NADA 042-427 for FINQUEL (tricaine methanesulfonate) and NADA 140-831 for PARACIDE-F (formalin).

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADAs

042-427 and 140-831, and all supplements and amendments thereto, is withdrawn. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Argent Laboratories will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for this firm.

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 529

Animal drugs.

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 510 and 529 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.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "Argent

Laboratories"; and in the table in paragraph (c)(2), remove the entry for "051212".

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 529 continues to read as follows:

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

4. In § 529.1030:

a. Revise paragraph (b);

b. Remove paragraphs (d)(1)(i) and (d)(1)(ii), and redesignate paragraphs (d)(1)(iii), (d)(1)(iv), and (d)(1)(v) as paragraphs (d)(1)(i), (d)(1)(ii), and (d)(1)(iii);

c. Remove paragraphs (d)(2)(i) and (d)(2)(ii), and redesignate paragraphs (d)(2)(iii), (d)(2)(iv), and (d)(2)(v) as paragraphs (d)(2)(i), (d)(2)(ii), and (d)(2)(iii); and

d. Revise the introductory text in newly designated paragraph (d)(2)(ii), and revise paragraph (d)(2)(iii).

The revisions read as follows:

§ 529.1030 Formalin.

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(b) Sponsors. See Nos. 049968, 050378, and 067188 in § 510.600(c) of this chapter.

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(d) * * *

(2) * * *

(ii) For control of external parasites on finfish:

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(iii) For control of fungi of the family Saprolegniaceae on finfish eggs: Eggs of all finfish except Acipenseriformes, 1,000 to 2,000 µL/L (ppm) for 15 minutes; eggs of Acipenseriformes,

up to 1,500 µL/L (ppm) for 15 minutes.

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5. Revise § 529.2503 to read as follows:

§ 529.2503 Tricaine methanesulfonate.

(a) Specifications. Ethyl-m-amino-benzoate methanesulfonate.

(b) Sponsor. See No. 050378 in § 510.600(c) of this chapter.

(c) Conditions of use. It is used as follows:

(1) Amount--(i) For fish the drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for the specific lots of fish under prevailing conditions.

(ii) For amphibians and other aquatic coldblooded animals, the drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(2) Indications for use. It is used for the temporary immobilization of fish, amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(3) Limitations. Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature should exceed 10 °C. (50 °F). In other fish and in cold-blooded animals, the

drug should be limited to hatchery or laboratory use.

Dated: January 10, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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