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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

Display Date 8-10-07
Publication Date 8-13-07
Certifier A. Corbin

Certain Other Dosage Form New Animal Drugs; Formalin

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 an abbreviated new animal drug application (ANADA) filed by B.L. Mitchell, Inc. The ANADA provides for the use of formalin in a water bath for the control of certain external parasites on finfish and shrimp and for the control of certain fungi on finfish eggs.

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

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756, filed ANADA 200-414 that provides for use of Formacide-B (formalin) in a water bath for the control of certain external parasites on finfish and shrimp and for the control of certain fungi on finfish eggs. B.L. Mitchell, Inc.'s Formacide-B is approved as a generic copy of Parasite-S, sponsored by Western Chemical, Inc., under NADA 140-989. The ANADA is approved as of July 17, 2007, and the regulations are amended in § 529.1030 to reflect the approval.

cv0750

2007-200-414

NFR 1

In addition, B.L. Mitchell, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this 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.

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.

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 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.

- 2. In § 510.600, in the table in paragraph (c)(1) alphabetically add a new entry for “B.L. Mitchell, Inc.”; and in the table in paragraph (c)(2) numerically add a new entry for “067188” 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
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756.	067188

(2) * * *

Drug labeler code	Firm name and address
067188	B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756

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.

§ 529.1030 [Amended]

■ 4. In paragraph (b)(1) of § 529.1030, remove “Nos. 049968 and 050378” and add in its place “Nos. 049968, 050378, and 067188”.

Dated: 8/1/07
August 1, 2007.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.
[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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