

PART 388—INFORMATION AND REQUESTS

1. The authority citation for part 388 continues to read as follows:

Authority: 5 U.S.C. 301–305, 551, 552 (as amended), 553–557; 42 U.S.C. 7101–7352.

2. In § 388.109, paragraph (a)(4)(i) is revised to read as follows:

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§ 388.109 Fees for record requests.

(a) * * *

(4)(i) The public may purchase hard copies of documents available in electronic form from the Commission's Federal Energy Regulatory Records Information System (FERRIS) for 20 cents per page.

[FR Doc. 02–10808 Filed 5–1–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three approved abbreviated new animal drug applications (ANADAs) from Blue Ridge Pharmaceuticals, Inc., to Virbac AH, Inc.

DATES: This rule is effective May 2, 2002.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Blue Ridge Pharmaceuticals, Inc., 4249–105 Piedmont Pkwy., Greensboro, NC 27410, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 200–270 for IVERHART (ivermectin) Tablets, NADA 200–281 for WORMEXX (pyrantel pamoate) Chewable Tablets, and NADA 200–302 for IVERHART Plus (ivermectin/pyrantel pamoate) Flavored Chewable Tablets to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137. Accordingly, the agency is amending the regulations in 21 CFR 520.1193,

520.1196, and 520.2041 to reflect the transfer of ownership.

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 in 21 CFR Part 520

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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1193 [Amended]

2. Section 520.1193 *Ivermectin tablets and chewables* is amended in paragraph (b)(2) by removing “065274” and by adding in its place “051311”.

§ 520.1196 [Amended]

3. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in the section heading by removing “tablet” and by adding in its place “tablets”; and in paragraph (b) by removing “065274” and by adding in its place “051311”.

§ 520.2041 [Amended]

4. Section 520.2041 *Pyrantel pamoate chewable tablets* is amended in paragraph (b) by removing “065274” and by adding in its place “051311”.

Dated: April 3, 2002..

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–10793 Filed 5–1–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tilmicosin

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 Elanco Animal Health. The supplemental NADA provides for additions to labeling of tilmicosin for use in swine feed.

DATES: This rule is effective May 2, 2002.

FOR FURTHER INFORMATION CONTACT:

Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–064 that provides for the use of PULMOTIL (tilmicosin phosphate) Type A medicated article in swine feed for the control of swine respiratory disease associated with certain bacterial organisms. The supplemental NADA provides for additional use information in labeling. The supplemental NADA is approved as of November 15, 2001, and the regulations are amended in 21 CFR 558.618 to reflect the approval.

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.

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 in 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 part 558 is amended as follows: