

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2008-N-0039]

Oral Dosage Form New Animal Drugs; Amprolium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Phibro Animal Health. The supplemental NADA provides for label revisions associated with a previous change of sponsorship and other minor changes for amprolium concentrate solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. The product approval is being codified for the first time.

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

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8343, e-mail: donald.prater@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660, filed a supplement to NADA 13-663 that provides for the use of COCCIPROL (amprolium) 9.6% Oral Solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. The supplemental NADA provides for label revisions associated with a previous change of sponsorship and other minor changes. The

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supplemental NADA is approved as of July 8, 2008, and the regulations are amended in 21 CFR 520.100 to reflect the approval. The product approval is being codified for the first time. Also, § 520.100 is revised to reflect current pathogen spelling.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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 Subject 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.

■ 2. In § 520.100, revise paragraph (b), remove paragraph (d), redesignate paragraph (e) as paragraph (d), and revise new paragraphs (d)(2)(i)(A) and (d)(2)(i)(B) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) *Sponsors*. See sponsors in 510.600(c) of this chapter.

(1) No. 016592 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) Nos. 051311 and 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(3) No. 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(2) of this section.

* * * * *

(d) * * *

(2) * * *

(i) * * * (A) As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*, administer 5 mg per kilogram (mg/kg) body weight for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard.

(B) As an aid in the treatment of coccidiosis caused by *E. bovis* and *E. zurnii*, administer 10 mg/kg body weight for 5 days.

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Dated: 7/28/08

July 28, 2008.

Dr. Bernadette Dunham

Bernadette Dunham,
Director,
Center for Veterinary Medicine.

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Supervisor