4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA-2011-N-0003]

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Topical Solution

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 Cross Vetpharm Group, Ltd. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites when cattle are treated with a topical solution of ivermectin.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to ANADA 200-318 for BIMECTIN (ivermectin) Pour-On, a topical solution used on cattle to control infestations of certain species of external and internal parasites. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites that were approved for the pioneer product with 3 years of marketing exclusivity (69 FR 501, January 6, 2004). The supplemental ANADA is approved as of September 21, 2011, and 21 CFR 524.1193 is amended to reflect the approval.

Approval of this supplemental ANADA 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 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 524

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 524 is amended as follows:

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1193 [Amended]

2. In § 524.1193, in paragraph (b)(1), in numerical sequence add “, and 061623”; and in paragraph (b)(2), remove “061623,”.

Dated: December 22, 2011.

Steven D. Vaughn,

Director,

Office of New Animal Drug Evaluation,

Center for Veterinary Medicine.

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