

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Pour-On

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 ECO LLC. The ANADA provides for topical use of ivermectin on cattle for treatment and control of various species of external and internal parasites.

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

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131, filed ANADA 200-348 for ECOMECTIN (ivermectin). The application provides for topical use of 0.5 percent ivermectin solution on cattle for the treatment and control of various species of gastrointestinal nematodes, lungworms, grubs, horn flies, lice, and mites. ECO's ECOMECTIN is approved as a generic copy of Merial Limited's IVOMEK Pour-On for Cattle, approved under NADA 140-841. The ANADA is approved as of November 15, 2002,

and 21 CFR 524.1193 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, ECO LLC has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the 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 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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 524

Animal drugs.

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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 524 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. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for “ECO LLC” and in the table in paragraph (c)(2) by numerically adding an entry for “066916” 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
* * * ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131. * * *	* * * 066916 * * *

(2) * * *

Drug labeler code	Firm name and address
* * * 066916 * * *	* * * ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131 * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1193 [Amended]

4. Section 524.1193 *Ivermectin pour-on* is amended in paragraph (b) by removing “and 059130” and by adding in its place “, 059130, and 066916”.

Dated: January 6, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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