

[illegible]

BILLING CODE 8010-01-P

FOR FURTHER INFORMATION CONTACT:
Thomas J. McKay, Center for Veterinary

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

(1) * * *

Firm name and address			Drug labeler code		
*	*	*	*	*	*
099207			Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258		
*	*	*	*	*	*

(2) * * *

Drug labeler code			Firm name and address		
*	*	*	*	*	*
099207			Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258		
*	*	*	*	*	*

Dated: May 29, 2000.
Claire M. Lathers,
*Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.*
[FR Doc. 00-14464 Filed 6-8-00; 8:45 am]
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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Parts 524 and 556

**Ophthalmic and Topical Dosage Form
New Animal Drugs; Moxidectin**

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 Fort Dodge Animal Health, Division of American Home Products Corp. The supplemental NADA provides for topical use of a 0.5 percent moxidectin solution on dairy cattle of breeding age for treatment and control of infections and infestations of certain internal and external parasites. FDA is also amending the regulations to establish a tolerance for moxidectin residues in milk.

DATES: This rule is effective June 9, 2000.

FOR FURTHER INFORMATION CONTACT:
Steven D. Vaughn, Center for Veterinary
Medicine (HFV-130), Food and Drug

Administration, 7500 Standish Pl.,
Rockville, MD 20855, 301-827-7584.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplemental NADA 141-099 that provides for use of Cydectin® (moxidectin) 0.5 percent pouron for dairy cattle at 500 micrograms moxidectin per kilogram of body weight for treatment and control of infections and infestations of certain gastrointestinal roundworms, lungworms, cattle grubs, mites, lice, and horn flies. The supplemental NADA is approved as of November 2, 1999, and the regulations are amended in 21 CFR 524.1451 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the regulations are amended in 21 CFR 556.426 to add a tolerance for residues of moxidectin in milk and, editorially, to reflect current format.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning

November 2, 1999, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 524

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 524 and 556 are amended as follows: