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]

BILLING CODE 4160–01–F

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:

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.

§ 524.1451 [Amended]

2. Section 524.1451 *Moxidectin* is amended in the first sentence of paragraph (d)(2) by removing the phrase ''Beef and non-lactating dairy cattle'' and by adding in its place the phrase ''Beef and dairy cattle'', and in paragraph (d)(3) by removing the first and second sentences.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.426 is revised to read as follows:

§ 556.426 Moxidectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of moxidectin is 4 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerance for parent moxidectin (the marker residue) in edible tissues of cattle is 200 parts per billion (ppb) in liver (the target tissue) and 50 ppb in muscle. The tolerance for parent moxidectin is 50 ppb in milk.

Dated: May 29, 2000.

Claire M. Lathers,

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

[FR Doc. 00–14463 Filed 6–8–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

State Plans: Coverage of the United States Postal Service and Other Coverage Issues—Changes to Level of Federal Enforcement for Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington and Wyoming

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule.

SUMMARY: This document amends OSHA's regulations to reflect declination of jurisdiction over the United States Postal Service (U.S. Postal Service or USPS) and its facilities by all twenty-three (23) approved State Plans which cover the private sector. The Postal Employees' Safety Enhancement Act of 1998 (PESEA) amended the Occupational Safety and Health Act of 1970 (the Act) to include the USPS within its definition of ''employer.'' Accordingly, OSHA assumed jurisdiction for the USPS on September 29, 1998. PESEA extends all provisions of the Act to the USPS, including section 18 of the Act, thus granting the OSHA-approved State plans the authority to regulate the USPS. Subsequently, OSHA required the State plan States to either elect to amend their State plans to cover the USPS, or to decline to exercise such coverage, in which case coverage would remain a Federal OSHA responsibility. All affected State plans declined. OSHA is hereby amending pertinent sections of its regulations on approved State plans to reflect the declination of State jurisdiction and the continuation of Federal OSHA enforcement authority over the USPS, including contract employees and contractor-operated facilities engaged in USPS mail operations, in all of the twenty-three (23) States operating OSHA-approved State plans covering the private sector, and notifying affected employers and employees of this action. As a result, Federal OSHA is responsible for safety and health enforcement with respect to the USPS and its facilities in all States nationwide. In addition, technical corrections are being made pertaining to maritime jurisdiction in several of the States; military jurisdiction in the State of Washington; coverage on Indian Reservations in the State of Oregon; and information on where the plan documents for the various State plans may be inspected.

EFFECTIVE DATE: June 9, 2000.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N3637, 200 Constitution Avenue NW, Washington, D.C. 20210, (202) 693–1999.

SUPPLEMENTARY INFORMATION:

Introduction

Section 18 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 667, provides that States which wish to assume responsibility for developing and enforcing their own occupational safety and health standards may do so by submitting and obtaining Federal approval of a State plan. State plan approval occurs in stages which include initial approval under section 18(c) of the Act and ultimately, final approval under section 18(e) of the Act. In the interim, between initial approval and final approval, there is a period of concurrent Federal/State jurisdiction within a State operating an approved plan. In the following States which have not received section 18(e) final approval, concurrent Federal enforcement authority remains in effect but has been suspended voluntarily in accordance with operational status agreements between OSHA and the individual States. See 29 CFR 1954.3 for guidelines and procedures. These States are: California, Michigan, New Mexico, Oregon, Puerto Rico, Vermont and Washington. In the following States which have received final approval pursuant to section 18(e) of the Act, Federal OSHA standards and enforcement authority have been relinquished. These States are: Alaska, Arizona, Hawaii, Indiana, Iowa, Kentucky, Maryland, Minnesota, Nevada, North Carolina, South Carolina, Tennessee, Utah, Virginia, and Wyoming. (Concurrent Federal enforcement authority is currently being exercised in the Virgin Islands. Connecticut and New York operate State plans limited in coverage to State and local government employees and are not affected by this rule.)

Background

United States Postal Service

States ordinarily cannot exercise regulatory authority over Federal agencies or other Federal institutions or