

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98-7596 Filed 3-23-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 528

New Animal Drugs For Use In Animal Feeds; Monensin; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations for monensin by removing the duplicate assay limits that appear in the regulations. This action is necessary to ensure the accuracy and consistency of the regulations.

EFFECTIVE DATE: March 24, 1998.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1739.

SUPPLEMENTARY INFORMATION: In the animal drug regulations, provisions for the assay limits for monensin liquid feeds were established in the regulations for medicated feed applications in § 558.4(d) (21 CFR 558.4(d)) in the Category I table and in the monensin regulation in § 558.355(c) (21 CFR 558.355(c)). In issuing the medicated feed regulations, assay limits were relegated to § 558.4(d) in the **Federal Register** of March 3, 1986 (51 FR 7382 at 7393). Inadvertently, the monensin liquid feed assay limits were also established in § 558.355(c). At this time, those limits in § 558.355(c) are removed and the paragraph reserved.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended by removing and reserving paragraph (c).

Dated: March 12, 1998.

Andrew J. Beaulieu,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

Change of Name and Address; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the name and address for the Association of Official Analytical Chemists International (AOAC). This action is editorial in nature, and is intended to provide accuracy and clarity to the agency's regulations.

EFFECTIVE DATE: March 24, 1998.

FOR FURTHER INFORMATION CONTACT: Lajuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR parts 101, 102, 106, 114, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 155, 156, 160, 161, 163, 164, 166, 168, and 169 to reflect a change in the name and address for AOAC. The current name and address listed in certain of FDA's regulations for AOAC is Association of Official Analytical Chemists, 2300 Wilson Blvd., suite 400, Arlington, VA 22201-3301. The new name and address is Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and under authority delegated to

the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

1. Parts 101, 102, 106, 114, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 155, 156, 160, 161, 163, 164, 166, 168, and 169 are amended by removing "Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301" wherever it appears and by adding in its place "Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504."

Dated: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 524 and 556

Animal Drugs, Feeds, and Related Products; 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 new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for topical use of a 0.5 percent solution of moxidectin on cattle for treatment and control of infections and infestations of certain internal and external parasites.

EFFECTIVE DATE: March 24, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, P.O. Box 400, Princeton, NJ 08543-0400, filed NADA 141-099 that provides for use of Cydectin® moxidectin 0.5 percent pour-on for beef and non-lactating 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 NADA is approved as of January 28, 1998, and the regulations are amended by adding § 524.1451 to reflect the approval. The basis for approval is discussed in the freedom of information summary.