By direction of the Commission.

Donald S. Clark,

Secretary.

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

BILLING CODE 6750–01–M

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. Beaulieau,

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

[FR Doc. 98–7495 Filed 3–23–98; 8:45 am]

BILLING CODE 4160–01–F

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.

[FR Doc. 98–7494 Filed 3–23–98; 8:45 am]

BILLING CODE 4160–01–F

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.

In addition, a tolerance for residues of moxidectin in edible tissues of cattle has not been previously established. At this time, a tolerance for moxidectin in edible cattle tissues is established in new section § 556.426.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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, this approval qualifies for 3 years of marketing exclusivity beginning January 28, 1998, 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.

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 the 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.

2. Section 524.1451 is added to read as follows:

§ 524.1451 Moxidectin.

(a) *Specifications.* Each milliliter contains 5 milligrams of moxidectin (0.5 percent solution).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Conditions of use.* (1) *Amount.* 0.5 milligrams moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use.* Beef and non-lactating dairy cattle for treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult), *Cooperia oncophora* (adult), *C. punctata* (adult), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult), *Nematodirus helvetianus* (adult)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (*Hypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. Communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Damalinia bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *O. ostertagi* for 28 days after treatment and with *D. viviparus* for 42 days after treatment.

(3) *Limitations.* Apply topically along the top of the back from the withers to the tailhead. Because a withdrawal time for milk has not been established, do not use on female dairy cattle of breeding age. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

PART 556—TOLERANCES FOR RESIDUES OF NEW 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 added to read as follows:

§ 556.426 Moxidectin.

An acceptable daily intake (ADI) of 4 micrograms per kilogram per day in tissue is established. A tolerance is established for parent moxidectin in edible tissues of cattle of 50 parts per billion in muscle and 200 parts per billion in liver.

Dated: March 13, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–7504 Filed 3–23–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05–98–016]

Special Local Regulations for Marine Events; Approaches to Annapolis Harbor, Spa Creek, and Severn River, Annapolis, MD

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements the special local regulations for the 19th Annual Safety at Sea Seminar, an annual marine event to be held March 28, 1998, on Spa Creek and the Severn River at Annapolis, Maryland. These special local regulations are necessary to control vessel traffic in the vicinity of the U.S. Naval Academy due to the confined nature of the waterway and expected vessel congestion during the fireworks display and helicopter rescue demonstration. The effect will be to restrict general navigation in the regulated area for the safety of spectators, event participants, and other vessels transiting the event area.

EFFECTIVE DATES: 33 CFR 100.511 is effective from 11:30 a.m. to 3 p.m. on March 28, 1998.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R.L. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore, MD 21226–1971, (410) 576–2674.

SUPPLEMENTARY INFORMATION: The U.S. Naval Academy Sailing Squadron will sponsor the 19th Annual Safety at Sea Seminar on the Severn River, near the U.S. Naval Academy, Annapolis, Maryland. Waterborne activities will include demonstrations of life rafts, pyrotechnics, man overboard procedures, and a helicopter rescue.

In order to ensure the safety of participants and transiting vessels, 33 CFR 100.511 will be in effect for the duration of the event. Under provisions of 33 CFR 100.511, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander. Spectator vessels may anchor outside the regulated area but may not block a