

Boston, MA, General Edward Lawrence Logan Intl, ILS OR LOC/DME RWY 15R, Amdt 1C

Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 4R, Amdt 1

Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 15R, Amdt 1

Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 22L, Amdt 1

Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 33L, Amdt 1

Boston, MA, General Edward Lawrence Logan Intl, VOR/DME-A, Amdt 1

Benton Harbor, MI, Southwest Michigan Rgnl, ILS OR LOC RWY 28, Amdt 7

Benton Harbor, MI, Southwest Michigan Rgnl, RNAV (GPS) RWY 10, Amdt 1A

Benton Harbor, MI, Southwest Michigan Rgnl, RNAV (GPS) RWY 28, Amdt 1

Detroit, MI, Detroit Metropolitan Wayne County, ILS OR LOC RWY 27L, Amdt 3

Detroit, MI, Detroit Metropolitan Wayne County, ILS OR LOC RWY 27R, Amdt 12

Detroit, MI, Detroit Metropolitan Wayne County, RNAV (GPS) RWY 27L, Amdt 2

Detroit, MI, Detroit Metropolitan Wayne County, RNAV (GPS) RWY 27R, Amdt 2

Gladwin, MI, Gladwin Zettel Memorial, NDB RWY 27, Amdt 4

Gladwin, MI, Gladwin Zettel Memorial, RNAV (GPS) RWY 9, Orig

Gladwin, MI, Gladwin Zettel Memorial, RNAV (GPS) RWY 27, Orig

Manistique, MI, Schoolcraft County, Takeoff Minimums and Obstacle DP, Orig

Bigfork, MN, Bigfork Muni, GPS RWY 15, Orig, CANCELLED

Bigfork, MN, Bigfork Muni, RNAV (GPS) RWY 15, Orig

Bigfork, MN, Bigfork Muni, RNAV (GPS) RWY 33, Orig

Greenwood, MS, Greenwood-Leflore, ILS OR LOC RWY 18, Amdt 7

Greenwood, MS, Greenwood-Leflore, RNAV (GPS) RWY 5, Amdt 1

Greenwood, MS, Greenwood-Leflore, VOR RWY 5, Amdt 12

Greenwood, MS, Greenwood-Leflore, Takeoff Minimums and Obstacle DP, Amdt 6

Yazoo City, MS, Yazoo County, Takeoff Minimums and Obstacle DP, Orig

Yazoo City, MS, Yazoo County, VOR/DME-B, Orig

Glasgow, MT, Wokal Field/Glasgow Intl, Takeoff Minimums and Obstacle DP, Orig

Wallace, NC, Henderson Field, NDB RWY 27, Amdt 1, CANCELLED

Caldwell, NJ, Essex County, NDB OR GPS-A, Amdt 5B, CANCELLED

Caldwell, NJ, Essex County, RNAV (GPS) RWY 4, Orig

Caldwell, NJ, Essex County, RNAV (GPS) RWY 10, Orig

Caldwell, NJ, Essex County, RNAV (GPS) RWY 22, Amdt 1

Rochester, NY, Greater Rochester Intl, RNAV (GPS) RWY 25, Orig-A

Ashtabula, OH, Ashtabula County, RNAV (GPS) RWY 9, Orig-A

Ashtabula, OH, Ashtabula County, RNAV (GPS) RWY 27, Orig-A

Ashtabula, OH, Ashtabula County, Takeoff Minimums and Obstacle DP, Orig-A

Youngstown/Warren, OH, Youngstown-Warren Rgnl, ILS OR LOC RWY 14, Amdt 8

Youngstown/Warren, OH, Youngstown-Warren Rgnl, ILS OR LOC RWY 32, Amdt 27

Youngstown/Warren, OH, Youngstown-Warren Rgnl, NDB RWY 32, Amdt 20

Youngstown/Warren, OH, Youngstown-Warren Rgnl, RNAV (GPS) RWY 32, Orig-A

Shawnee, OK, Shawnee, RNAV (GPS) RWY 35, Orig-A

Pelion, SC, Lexington County at Pelion, RNAV (GPS) RWY 18, Orig

Pelion, SC, Lexington County at Pelion, RNAV (GPS) RWY 36, Orig

Pelion, SC, Lexington County at Pelion, VOR-A, Amdt 3

Spartanburg, SC, Spartanburg Downtown Memorial, ILS OR LOC RWY 5, Amdt 1

Spartanburg, SC, Spartanburg Downtown Memorial, NDB OR GPS-A, Amdt 8C, CANCELLED

Spartanburg, SC, Spartanburg Downtown Memorial, RNAV (GPS) RWY 5, Orig

Spartanburg, SC, Spartanburg Downtown Memorial, RNAV (GPS) RWY 23, Orig

Spartanburg, SC, Spartanburg Downtown Memorial, Takeoff Minimums and Obstacle DP, Amdt 1

Gallatin, TN, Sumner County Rgnl, RNAV (GPS) RWY 17, Amdt 1

Gallatin, TN, Sumner County Rgnl, RNAV (GPS) RWY 35, Amdt 1

Rockwood, TN, Rockwood Muni, RNAV (GPS) RWY 4, Orig

Rockwood, TN, Rockwood Muni, RNAV (GPS) RWY 22, Amdt 1

Rockwood, TN, Rockwood Muni, Takeoff Minimums and Obstacle DP, Amdt 2

Crockett, TX, Houston County, GPS RWY 2, Orig-A, CANCELLED

Crockett, TX, Houston County, GPS RWY 20, Orig-A, CANCELLED

Crockett, TX, Houston County, RNAV (GPS) RWY 2, Orig

Crockett, TX, Houston County, RNAV (GPS) RWY 20, Orig

Crockett, TX, Houston County, Takeoff Minimums and Obstacle DP, Orig

Dallas-Fort Worth, TX, Dallas/Fort Worth Intl, ILS OR LOC RWY 13R, ILS RWY 13R (SA CAT II), Amdt 8

Dallas-Fort Worth, TX, Dallas/Fort Worth Intl, RNAV (RNP) Z RWY 13R, Orig-D

Lamesa, TX, Lamesa Muni, NDB RWY 16, Amdt 3

Lamesa, TX, Lamesa Muni, NDB RWY 34, Amdt 4

Lamesa, TX, Lamesa Muni, RNAV (GPS) RWY 16, Orig

Lamesa, TX, Lamesa Muni, RNAV (GPS) RWY 34, Orig

Wichita Falls, TX, Wichita Valley, VOR/DME-C, Amdt 2

Logan, UT, Logan-Cache, RNAV (GPS) RWY 17, Amdt 1

Galax/Hillsville, VA, Twin County, Takeoff Minimums and Obstacle DP, Amdt 2

Lawrenceville, VA, Lawrenceville/Brunswick Muni, RNAV (GPS) RWY 18, Orig-A

Lawrenceville, VA, Lawrenceville/Brunswick Muni, RNAV (GPS) RWY 36, Orig-A

Moneta, VA, Smith Mountain Lake, RNAV (GPS) RWY 23, Orig-A

Moneta, VA, Smith Mountain Lake, VOR/DME OR GPS RWY 23, Orig-A, CANCELLED

Richlands, VA, Tazewell County, Takeoff Minimums and Obstacle DP, Amdt 1

Spokane, WA, Spokane Intl, ILS OR LOC/DME RWY 21, ILS RWY 21 (SA CAT I), ILS RWY 21 (CAT II), ILS RWY 21 (CAT III), Amdt 23

Spokane, WA, Spokane Intl, RNAV (GPS) Y RWY 3, Amdt 2A

Spokane, WA, Spokane Intl, RNAV (GPS) Y RWY 21, Amdt 2

Spokane, WA, Spokane Intl, RNAV (RNP) Z RWY 21, Amdt 1

Hartford, WI, Hartford Muni, NDB OR GPS RWY 11, Amdt 4A, CANCELLED

Hartford, WI, Hartford Muni, RNAV (GPS) RWY 11, Orig

Hartford, WI, Hartford Muni, RNAV (GPS) RWY 29, Orig

Hartford, WI, Hartford Muni, Takeoff Minimums and Obstacle DP, Orig

Hartford, WI, Hartford Muni, VOR OR GPS-A, Amdt 5A, CANCELLED

Menomonie, WI, Menomonie Muni-Score Field, Takeoff Minimums and Obstacle DP, Amdt 1

New Richmond, WI, New Richmond Rgnl, RNAV (GPS) RWY 14, Amdt 2A

Phillips, WI, Price County, NDB OR GPS RWY 6, Amdt 1A, CANCELLED

Phillips, WI, Price County, NDB OR GPS RWY 24, Amdt 3A, CANCELLED

Phillips, WI, Price County, RNAV (GPS) RWY 6, Orig

Phillips, WI, Price County, RNAV (GPS) RWY 24, Orig

Waukesha, WI, Waukesha County, ILS OR LOC RWY 10, Amdt 2

Summersville, WV, Summersville, GPS RWY 4, Amdt 2A, CANCELLED

Summersville, WV, Summersville, GPS RWY 22, Amdt 2A, CANCELLED

Summersville, WV, Summersville, RNAV (GPS) RWY 4, Orig

[FR Doc. 2011-30073 Filed 11-23-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 522, and 556

[Docket No. FDA-2011-N-0003]

Animal Drugs, Feeds, and Related Products; Eprinomectin; N-Methyl-2-Pyrrolidone

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 original new animal drug application (NADA) filed by Merial Ltd. The NADA provides for the veterinary prescription use of eprinomectin by

injection for the treatment and control of internal and external parasites of cattle on pasture with persistent effectiveness. The current tolerance for the marker residue for total residues of eprinomectin in edible tissues of cattle is being lowered. The method of detection for residues of the carcinogenic excipient *n*-methyl-2-pyrrolidone (NMP) in edible tissues of cattle is also being codified.

DATES: This rule is effective November 25, 2011. The incorporation by reference of a certain method listed in this rule is approved by the Director of the **Federal Register** as of November 25, 2011.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276-8341, email:

cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640 filed NADA 141-327 that provides for veterinary prescription use of LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide for the treatment and control of internal and external parasites of cattle on pasture with persistent effectiveness. The NADA is approved as of September 26, 2011, and the regulations are amended in 21 CFR part 522 to reflect the approval.

As a consequence of the residue depletion characteristics of this product, the current tolerance for the marker residue for eprinomectin in the target tissue of cattle is being lowered. Accordingly, the regulations are amended in 21 CFR part 556. Elsewhere in this issue of the **Federal Register**, the approved NADA for an eprinomectin topical solution used on cattle is being supplemented to provide for this lower tolerance.

In addition, FDA has determined that an inactive ingredient in this product, the excipient *n*-methyl-2-pyrrolidone (NMP), is a carcinogen. As required by section 512(d)(1)(I) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(d)(1)(I)), a method of detection for residues of NMP in edible tissues of cattle is being codified in 21 CFR part 500, new subpart F, through incorporation by reference.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (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 FD&C Act, this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management 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 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs), Incorporation by reference.

21 CFR Part 522

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 500, 522, and 556 are amended as follows:

PART 500—GENERAL

■ 1. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371.

■ 2. Add subpart F, consisting of § 500.1410, to read as follows:

Subpart F—Methods for Detection of Residues of Carcinogenic Compounds Used in Food-Producing Animals

§ 500.1410 N-methyl-2-pyrrolidone.

(a) *Standard for residues.* No residues of *n*-methyl-2-pyrrolidone may be found in the uncooked edible tissues of cattle as determined by a method entitled "Method of Analysis: *N*-methyl-2-pyrrolidone," September 26, 2011, Center for Veterinary Medicine, Food and Drug Administration, which is incorporated by reference with the approval of the Director of the Federal Register under 5 U.S.C. 522(a) and 1 CFR part 51. You may obtain a copy of

the method from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; (240) 276-9120; or go to: <http://www.fda.gov/aboutfda/centersoffices/cvm/cvmfoiaelectronicreadingroom/default.htm>. You may inspect a copy at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, (301) 827-6860, between 9 a.m. and 4 p.m., Monday through Friday or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(b) *Related conditions of use.* See §§ 522.814 and 522.955 of this chapter.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. Add § 522.814 to read as follows:

§ 522.814 Eprinomectin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) eprinomectin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 500.1410 and 556.227 of this chapter.

(d) *Conditions of use in cattle on pasture—*(1) *Amount.* Administer 1 mg/kilogram of body weight by subcutaneous injection.

(2) *Indications for use.* For the treatment and control of the following internal and external parasites: Gastrointestinal roundworms (adults and fourth-stage larvae) *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Trichostrongylus axei*, *Ostertagia ostertagi* (including inhibited stage); (adults) *Haemonchus placei*, *Oesophagostomum radiatum*, *O. lyrata*, *T. colubriformis*; lungworms (adults) *Dictyocaulus viviparus*; cattle grubs *Hypoderma bovis*; mites *Sarcoptes scabiei* var. *bovis*. Prevents reinfection with *C. oncophora*, *C. punctata*, and *T. axei* for 100 days following treatment; *H. placei*, *O. radiatum*, *O. lyrata*, and *O. ostertagi* for 120 days following treatment; and *D. viviparus* for 150 days following treatment.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Animals

intended for human consumption must not be slaughtered within 48 days of the last treatment. Do not use in female dairy cattle 20 months of age or older. Use in lactating dairy cows may cause drug residues in milk. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

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

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

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

■ 6. In § 556.227, revise paragraph (b) and add paragraph (c) to read as follows:

§ 556.227 Eprinomectin.

* * * * *

(b) *Tolerances.* The tolerances for eprinomectin B_{1a} (marker residue) are:

(1) *Cattle*—(i) *Liver (target tissue):* 1.5 parts per million.

(ii) *Muscle:* 100 parts per billion (ppb).

(iii) *Milk:* 12 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.814 and 524.814 of this chapter.

Dated: November 17, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–30329 Filed 11–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA–2011–N–0003]

Ophthalmic and Topical Dosage Form New Animal Drugs; Eprinomectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Merial Ltd. The supplemental NADA provides for addition of a warning statement against the use of eprinomectin topical solution in preruminating calves intended for veal.

DATES: This rule is effective November 25, 2011.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for

Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8341, email:

cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640 filed a supplement to NADA 141–079 for EPRINEX (eprinomectin) Pour-On for Beef and Dairy Cattle, a topical solution used for the treatment and control of internal and external parasites of cattle on pasture with persistent effectiveness. The supplemental NADA provides for addition of a warning statement against the use of eprinomectin topical solution in preruminating calves intended for veal. The NADA is approved as of September 23, 2011, and the regulations are amended in 21 CFR part 524 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The Agency has determined under 21 CFR 25.33 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 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 in 21 CFR Part 524

Animal drugs.

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 524 is 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. Revise § 524.814 to read as follows:

§ 524.814 Eprinomectin.

(a) *Specifications.* Each milliliter (mL) contains 5 milligrams (mg) of eprinomectin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.227 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Apply 5 mg (1 mL) per 10 kilograms (kg) of body weight (500 micrograms/kg) applied topically along backbone from withers to tailhead.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms (*Haemonchus placei* (adult and L4), *Ostertagia ostertagi* (adult and L4, including inhibited L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *T. longispicularis* (adult), *Cooperia oncophora* (adult and L4), *C. punctata* (adult and L4), *C. surnabada* (adult and L4), *Nematodirus helvetianus* (adult and L4), *Bunostomum phlebotomum* (adult and L4), *Oesophagostomum radiatum* (adult and L4), *Strongyloides papillosus* (adults), *Trichuris* spp. (adults)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (all parasitic stages *Hypoderma lineatum*, *H. bovis*); lice (*Damalinia bovis*, *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mange mites (*Chorioptes bovis*, *Sarcoptes scabiei*); and horn flies (*Haematobia irritans*). Controls and protects from reinfection of *D. viviparus* for 21 days after treatment and *H. irritans* for 7 days after treatment.

(3) *Limitations.* A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

Dated: November 18, 2011.

Steven D. Vaughn,

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

[FR Doc. 2011–30328 Filed 11–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[TD 9559]

RIN 1545–BK24

User Fee To Take the Registered Tax Return Preparer Competency Examination

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains amendments to the user fee regulations. The final regulations redesignate rules pertaining to fees for obtaining a preparer tax identification number. These final regulations also establish a