SUMMARY:

The NADA provides for the veterinary

Food and Drug Administration,

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 522, and 556

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

Pyrrolidone

Animal Drugs, Feeds, and Related

Food and Drug Administration

HUMAN SERVICES

BILLING CODE 4910–13–P

Federal Register / Vol. 76, No. 227 / Friday, November 25, 2011 / Rules and Regulations 72617

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 3

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-A
Pelion, SC, Lexington County at Pelion, RNAV (GPS) RWY 36, Orig-A
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-A
Spartanburg, SC, Spartanburg Downtown Memorial, RNAV (GPS) RWY 23, Orig-A
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-A
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, RNAV (GPS) RWY 2, Orig-A, CANCELLED
Crockett, TX, Houston County, RNAV (GPS) RWY 20, Orig-A, CANCELLED
Crockett, TX, Houston County, RNAV (GPS) RWY 2, Orig-A, CANCELLED
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/Brussels Muni, RNAV (GPS) RWY 18, Orig-A
Lawrenceville, VA, Lawrenceville/Brussels Muni, RNAV (GPS) RWY 36, Orig-A
Moneta, VA, Smith Mountain Lake, RNAV (GPS) RWY 23, Orig-A

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
Hartford, WI, Hartford Muni, NDB OR GPS RWY 11, Amdt 4A, CANCELLED
Hartford, WI, Hartford Muni, RNAV (GPS) RWY 11, Orig-A
Hartford, WI, Hartford Muni, Takeoff Minimums and Obstacle DP, Orig-A
Hartford, WI, Hartford Muni, VOR OR GPS-A, Amdt 5A, CANCELLED
Monomonic, WI, Monomonic 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-A
Phillips, WI, Price County, RNAV (GPS) RWY 24, Orig-A
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-A

[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


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

Phillips, WI, Price County, NDB OR GPS RWY 24, Orig-A

Logan Intl, RNAV (GPS) Y RWY 21, Orig-A
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)(D) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(d)(1)(D)), 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 re-delegated to the Center for Veterinary Medicine, 21 CFR parts 500, 522, and 556 are amended as follows:

PART 500—GENERAL

§ 500.1410 N-methyl-2-pyrrolidione.

(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/cvm/cvmfoiaelectronicroom/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) 287–6600, 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.
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 pre-ruminating 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:


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

§556.227 Eprinomectin.

(b) Tolerances. The tolerances for eprinomectin B14 (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.

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 pre-ruminating 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.

The final regulations redesignate rules of ''particular applicability.''

Applicable to pre-ruminating calves intended for veal. Do not use in calves to be processed for veal.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS

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


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

§556.227 Eprinomectin.

(b) Tolerances. The tolerances for eprinomectin B14 (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.

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

Dated: November 17, 2011.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

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 pre-ruminating 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.

The final regulations redesignate rules of ''particular applicability.''

Applicable to pre-ruminating calves intended for veal. Do not use in calves to be processed for veal.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS

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


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

§556.227 Eprinomectin.

(b) Tolerances. The tolerances for eprinomectin B14 (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.

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

Dated: November 17, 2011.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

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 pre-ruminating 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.

The final regulations redesignate rules of ''particular applicability.''

Applicable to pre-ruminating calves intended for veal. Do not use in calves to be processed for veal.