



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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of a certain method listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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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 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:

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.

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