

cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

§ 522.1451 [Amended]

■ 3. Section 522.1451 is amended by revising the section heading to read "Moxidectin for suspension."

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

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

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

■ 5. Section 556.426 is amended by redesignating paragraphs (b)(1)(i) through (b)(1)(iii) as paragraphs (b)(1)(ii) through (b)(1)(iv); by revising newly redesignated paragraphs (b)(1)(ii) and (b)(1)(iv); and by adding new paragraphs (b)(1)(i) and (c) to read as follows:

§ 556.426 Moxidectin.

* * * * *

(b) * * *

(1) * * *

(i) *Fat (the target tissue)*. The tolerance for parent moxidectin (the marker residue) is 900 parts per billion (ppb).

(ii) *Liver*. The tolerance for parent moxidectin (the marker residue) is 200 ppb.

(iii) * * *

(iv) *Milk*. The tolerance for parent moxidectin (the marker residue) is 40 ppb.

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(c) *Related conditions of use*. See § 522.1451 of this chapter.

Dated: June 10, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Mometasone Furoate, Clotrimazole Otic Suspension; 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 to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for a new container size, a 7.5-gram dropper bottle, from which gentamicin sulfate, mometasone furoate, clotrimazole otic suspension may be administered for the treatment of otitis externa in dogs. The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective June 23, 2005.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 141-177 for use of MOMETAMAX (gentamicin sulfate, U.S.P.; mometasone furoate monohydrate; and clotrimazole, U.S.P.) Otic Suspension for the treatment of otitis externa in dogs. The supplement provides for a new container size, a 7.5-gram dropper bottle. The supplemental NADA is approved as of June 1, 2005, and the regulations are amended in 21 CFR 524.1044h to reflect the approval.

The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

The agency has determined under 21 CFR 25.33(a)(4) 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 an 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 Subject 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. Section 524.1044h is amended by revising paragraphs (b) and (c)(1) to read as follows:

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

* * * * *

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

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Dated: June 15, 2005.

Steven D. Vaughn,

Director, Office of New Animal Drug

Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1306

[Docket No. DEA-202F]

RIN 1117-AA68

Authority for Practitioners To Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is amending its regulations to allow qualified practitioners not otherwise registered as a narcotic treatment program to dispense and prescribe to narcotic dependent persons Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment. This Final Rule is in response to amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA) that are designed to expand and