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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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Certifier A. Corbin

New Animal Drugs For Use in Animal Feeds; Ivermectin

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 supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA revises the approved concentration of ivermectin in Type C medicated feed administered as a top dress to adult and breeding swine for the treatment and control of various internal and external parasites.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed a supplement to NADA 140-974 that provides for use of IVOMEK (ivermectin) Premix for Swine, a Type A medicated article, for the treatment and control of various internal and external parasites. The supplement revises the approved concentration of ivermectin in Type C medicated feed administered as a top dress to adult and breeding swine. The supplemental NADA is approved as of June 15, 2007, and the regulations in 21 CFR 558.300 are amended to reflect the approval and a current format.

2007-140-974

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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.

FDA has determined under 21 CFR 25.33(a)(1) 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 Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 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.

■ 2. Revise § 558.300 to read as follows:

§ 558.300 Ivermectin.

(a) *Specifications.* Type A medicated article containing 2.72 grams ivermectin per pound (g/lb).

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

(c) *Related tolerances.* See § 556.344 of this chapter.

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

(e) Conditions of use in swine. It is used in feed as follows:

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(1) 1.8 (to provide 0.1 milligram per kilogram (mg/kg) of body weight per day)		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); threadworms (<i>Strongyloides ransomi</i> , adults and somatic larvae); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(2) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 10 to 30	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for increased rate of weight gain and improved feed efficiency.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(3) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 250	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(4) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 20	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>); and for increased rate of weight gain.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Withdraw 5 days before slaughter. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(5) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 40	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter. Withdraw 5 days before slaughter. A separate feed containing 40 g/ton lincomycin may be continued to complete the lincomycin treatment.	050604
(6) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 100	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for treatment of swine dysentery.	Feed as the only feed for 7 consecutive days followed by a separate feed containing 100 g/ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(7) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 200	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for reduction in severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> .	Feed as the only feed for 7 consecutive days followed by a separate feed containing 200 g/ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(8) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); threadworms (<i>Strongyloides ransomi</i> , adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(9) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 250	Pregnant sows: As in paragraph (e)(8) of this section; and for control of clostridial enteritis caused by <i>Clostridium perfringens</i> in suckling piglets.	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter. Feed bacitracin methylene disalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604
(10) 18.2 to 120 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: As in paragraph (e)(8) of this section.	Top dress on daily ration for individual treatment for 7 consecutive days. Withdraw 5 days before slaughter.	050604

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