

Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.538 [Amended]

■ 2. In paragraph (a) of § 520.538, remove “25 or 100 milligrams” and in its place add “25, 75, or 100 milligrams”.

Dated: June 24, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–13372 Filed 7–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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 July 10, 2007.

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.

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

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(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

Dated: June 27, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-13369 Filed 7-9-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300 and 1315

[Docket No. DEA-2931]

RIN 1117-AB08

Import and Production Quotas for Certain List I Chemicals

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: In March 2006, Congress enacted the Combat Methamphetamine Epidemic Act of 2005, which mandates that DEA establish total annual requirements, import quotas, individual manufacturing quotas, and procurement quotas for three List I chemicals—ephedrine, pseudoephedrine, and phenylpropanolamine. DEA is promulgating this rule to incorporate the statutory provisions and make its regulations consistent with the new requirements.

DATES: Effective Date: July 10, 2007.
Comment Date: Written comments must be postmarked on or before September 10, 2007.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-293" on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537,

Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase "CONFIDENTIAL BUSINESS

INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on <http://www.regulations.gov>.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and placed in the agency's public docket file, and, where possible, posted online. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Additional Information" paragraph.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 at (202) 307-7183.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes, for lawful exports, and for maintenance of reserve stocks while deterring the diversion of controlled substances to illegal purposes. The CSA mandates that DEA