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

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

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

4. Section 556.360 is revised to read as follows:

§ 556.360 Lincomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

(b) *Chickens.* A tolerance for residues of lincomycin in chickens is not required.

(c) *Swine.* Tolerances for lincomycin of 0.6 part per million in liver and 0.1 part per million in muscle are established.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.325 [Amended]

6. Section 558.325 *Lincomycin* is amended by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), in newly redesignated paragraph (d)(2)(ii)(*b*) by removing ''; feed containing 100 grams per ton lincomycin hydrochloride should be withdrawn 6 days before slaughter'', and in newly redesignated paragraphs (d)(2)(iii)(*b*) and (d)(2)(iv)(*b*) by removing ''; withdraw 6 days before slaughter''.

Dated: March 2, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–6530 Filed 3–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Ivermectin and Bacitracin Methylene Disalicylate

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 new animal drug application (NADA) filed by Merial Ltd. The NADA provides for use of ivermectin and bacitracin methylene disalicylate (BMD) Type A medicated articles to make Type B and Type C medicated swine feeds for use as antiparasitics, antibacterials, and growth promotants.

EFFECTIVE DATE: March 18, 1999.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, filed NADA 141–097 that provides for use of Ivomec® (ivermectin 0.6 percent) and BMD (BMD 30, 50, 60, and 75 grams(g) per pound) Type A medicated articles to make ivermectin and BMD Type B and Type C medicated swine feeds. The Type C medicated feeds contain 1.8 g of ivermectin and 10, 30, or 250 g of BMD per ton for feeding to growing and finishing swine, and pregnant sows. It is used for the treatment and control of gastrointestinal roundworms, kidneyworms, lungworms, and threadworm infections; lice and mange mite infestations; increased rate of weight gain and improved feed efficiency; and for the control of clostridial enteritis and swine dysentery. The NADA is approved as of February 3, 1999, and the regulations are amended in 21 CFR 558.76 and § 558.300 (21 CFR 558.300) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, the regulation concerning the limitations for use of ivermectin feeds in § 558.300(d) are editorially amended by removing ''sole ration'' and adding in its place ''only feed''.

This NADA is for use of approved ivermectin and BMD Type A medicated articles to make Type B and Type C medicated swine feeds. Ivermectin is a category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved medicated feed application is required for making Type B or Type C medicated feeds as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by the requirement for feed mill licenses. Therefore, use of ivermectin and BMD Type A medicated articles to make Type B and Type C medicated feeds as in this NADA is limited to manufacture in a licensed feed mill.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (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.

The agency has determined under 21 CFR 25.33(a)(2) 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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 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. Section 558.76 is amended by adding paragraph (d)(3)(xx) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xx) Ivermectin as in § 558.300.

3. Section 558.300 is amended in paragraphs (d)(1)(ii), (d)(2)(ii), (d)(3)(ii), (d)(4)(ii), and (d)(5)(ii) by removing the phrase ''sole ration'' and adding in its place the phrase ''only feed'', and by adding new paragraph (d)(6) to read as follows:

§ 558.300 Ivermectin.

* * * * *

(d) * * *

(6) *Amount per ton.* For weaned, growing-finishing pigs, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day), and 10 to 30 or 250 grams of bacitracin methylene disalicylate. For adult and breeding swine, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day), and 10 to 30 or 250 grams of bacitracin methylene disalicylate.

(i) *Indications for use.* For treatment and control of gastrointestinal

roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*). For increased rate of weight gain and improved feed efficiency in growing and finishing swine. For control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets. For control of swine dysentery associated with *Treponema hypdysenteriae* on premises with a history of swine dysentery but where signs of disease have not yet occurred, or following an approved treatment of disease condition.

(ii) *Limitations.* For use in swine feed only. Feed as the only feed for 7 consecutive days. For weaned growing and finishing swine, feed bacitracin methylene disalicylate Type C medicated feed from weaning to market weight for increased rate of weight gain and improved feed efficiency. For pregnant sows, feed bacitracin methylene disalicylate to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Withdraw ivermectin-containing feeds 5 days before slaughter.

Dated: February 26, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–6527 Filed 3–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 256

Outer Continental Shelf Regulations

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Correction to correcting amendments.

SUMMARY: This document contains a correction to the correcting amendments which were published on February 24, 1999 (64 FR 9065). These regulations relate to leasing in the Outer Continental Shelf (OCS), 30 CFR part 256.

EFFECTIVE DATE: March 18, 1999.

FOR FURTHER INFORMATION CONTACT: Kumkum Ray (703) 787–1600.

SUPPLEMENTARY INFORMATION: As published, the correcting amendments contain an error which is inaccurate and needs to be clarified. The correcting amendments document contained several technical revisions to citations listed throughout title 30 of the Code of Federal Regulations. The document incorrectly indicated ''§ 256.76(a)(3)'' was revised; it should have revised ''§ 256.77(d)(3).''

Correction of Publication

Accordingly, the publication on February 24, 1999, 64 FR 9065, which was the subject of FR Doc. 99–4599, is corrected as follows:

On page 9066, in the second column, amendatory instruction number 7 is corrected to read as follows:

§ 256.77 [Corrected]

7. In § 256.77(d)(3), the citation ''250.12'' is revised to read ''250.112''.

Dated: March 10, 1999.

John Mirabella,

Acting Chief, Engineering and Operations Division.

[FR Doc. 99–6610 Filed 3–17–99; 8:45am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IA 059–1059a; FRL–6310–7]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving a revision to the Iowa State Implementation Plan (SIP) which provides for the attainment and maintenance of the particulate matter (PM_{10}) National Ambient Air Quality Standard (NAAQS) in Buffalo, Iowa. This revision approves two state Administrative Consent Orders (ACOs) which require reductions of PM_{10} emissions from two major sources of PM in Buffalo, Iowa. Approval of this SIP revision will make the state ACOs Federally enforceable.

DATES: This direct final rule is effective on May 17, 1999 without further notice, unless the EPA receives adverse comment by April 19, 1999. If adverse comment is received, the EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Comments may be addressed to Wayne Kaiser, Environmental Protection Agency, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

Copies of the state submittal are available at the following addresses for inspection during normal business hours: Environmental Protection Agency, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101; and the Environmental Protection Agency, Air and Radiation Docket and Information Center, Air Docket (6102), 401 M Street, SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Wayne Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION: This section provides additional information by answering the following questions:

What is an SIP?
What is the NAAQS?
What air quality problems occurred in Buffalo, Iowa?
How was the problem addressed?
What is the control strategy?
Is the SIP revision approvable?
What are the Section 172(e) requirements?

Additional information is contained in the state submittal and in the EPA technical support document for this notice which can be obtained by contacting the EPA at the address above.

What Is an SIP?

Each state has an SIP containing rules, control measures, and strategies used to attain and maintain the NAAQS. The SIP is frequently updated by the state in order to maintain a current and effective air pollution control program and to keep current with ongoing Federal requirements. The EPA must review and approve revisions to the state SIP. The Iowa SIP is published in 40 Code of Federal Regulations (CFR) Part 52, Subpart Q. The state of Iowa has submitted the control measures discussed below for approval in the Iowa SIP. Once measures have been approved in the SIP, the EPA has the authority to directly enforce the approved control measures.

What Is the NAAQS?

The EPA has established NAAQS for a number of pollutants including PM. These standards are set at levels to protect public health and welfare. The standards are published in 40 CFR Part 50. If ambient air monitors measure violations of the standard, states are