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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Approval Date	3-17-99
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Certifier	JAWINDSO

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, antibacterial, and growth promotants.

EFFECTIVE DATE: (Insert *date of publication in the Federal Register.*)

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pi., 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 514.110, 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 redelegate 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.

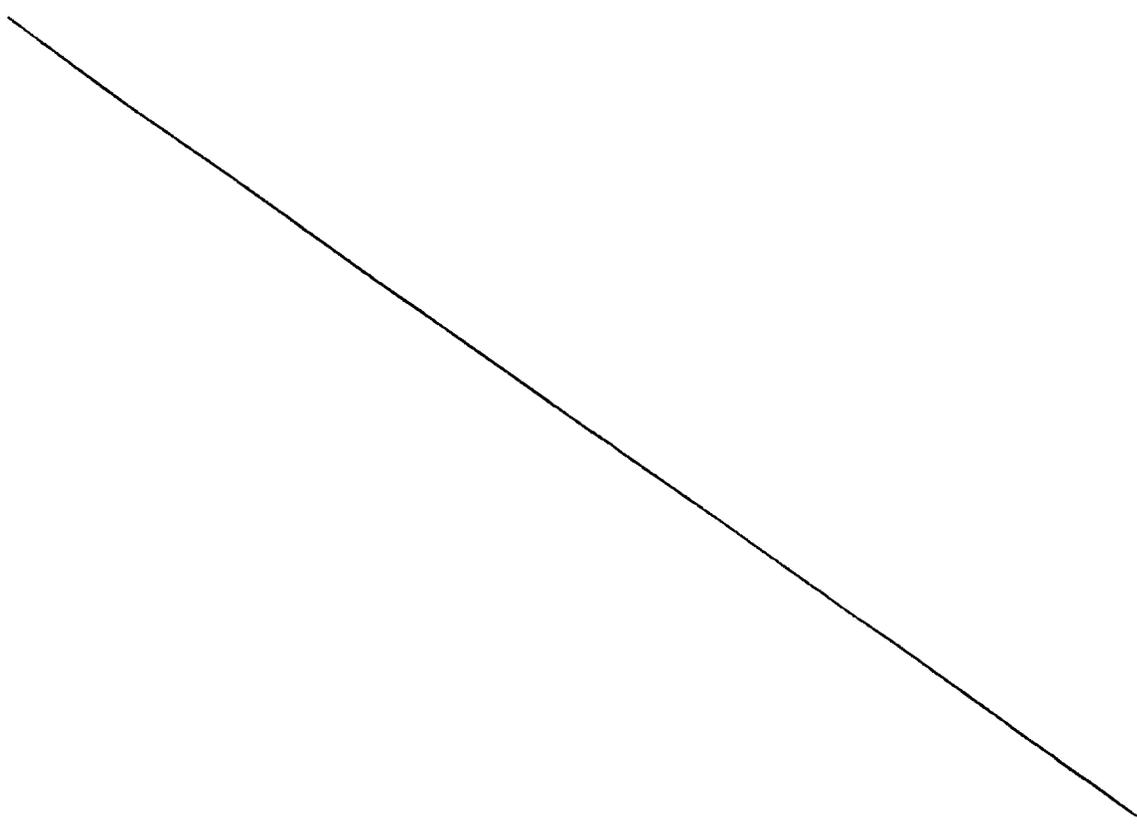
* * * * *

(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; *Hyostrogylus 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 hypodysenteriae* 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.

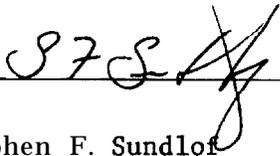


For pregnant sows, feed bacitracin methylene disalicylate to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Withdraw ivermectin-containing feeds 5 days before slaughter.

Dated: 2/26/99

February 26, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Stephen F. Sundlof
Director, Center for Veterinary Medicine

[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

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