

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bacitracin Methylene Disalicylate; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) that appeared in the **Federal Register** of August 18, 2004 (69 FR 51172). FDA is removing the drug labeler code for Pennfield Oil Co. in the entry for use of single-ingredient bacitracin methylene disalicylate (BMD) in swine feed, which was added in error during document formatting; and is adding the approved source of BMD in the entry for use of BMD in combination with chlortetracycline. These corrections are being made so the BMD regulations accurately reflect approved new animal drug applications.

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

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: *ghaibel@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: For the reasons set forth in the preamble, FDA is correcting 21 CFR part 558 to read as follows:

DDM
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Certifier D. Hawkins

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 in the table by revising paragraph (d)(1)(iv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(1) * * *

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iv) 10 to 30	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day.	Swine; for increased rate of weight gain and improved feed efficiency. Swine; for increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. Swine; for control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline.	For growing and finishing swine Feed for not more than 14 days; bacitracin methylene disalicylate provided by No. 046573; chlortetracycline provided by Nos. 046573 and 053389 in § 510.600(c) of this chapter. Feed for not more than 14 days; chlortetracycline and BMD as provided by 046573 in § 510.600(c) of this chapter.	046573 046573 053389 046573

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Dated: 9/2/04
September 2, 2004.

cv0474:

JD

SF Sundlof

Stephen F. Sundlof,
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[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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