

not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

Dated: August 27, 1998.
Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
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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 and Decoquinat

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 Alpharma Inc. The NADA provides for using approved bacitracin methylene disalicylate (BMD) and decoquinat Type A medicated articles to make Type C medicated broiler chicken feeds used

for prevention of coccidiosis, and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: September 29, 1998.
FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1600.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-102 that provides for combining approved BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) BMD), and Deccox® (6 percent decoquinat) Type A medicated articles to make Type C medicated feeds for broiler chickens containing 4 to 50 grams per ton (g/t) BMD and 27.2 g/t decoquinat. The Type C medicated broiler feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of August 3, 1998, and the regulations in 21 CFR 558.76(d)(3) and the table in 21 CFR 558.195(d) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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

§ 558.76 Bacitracin methylene disalicylate.
* * * * *
(d) * * *
(3) * * *
(xviii) Decoquinat as in § 558.195.
3. Section 558.195 is amended in the table in paragraph (d) by adding an entry under “27.2(0.003 pct)” before the entry for “Bacitracin 10 to 50” to read as follows:

§ 558.195 Decoquinat.
* * * * *
(d) * * *

Decoquinat in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* 27.2 (0.003 pct) *	* * Bacitracin 4 to 50	* * Broiler chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> , and for increased rate of weight gain and improved feed efficiency.	* * Do not feed to laying chickens; feed continuously as sole ration; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	* * 046573
*	*	*	*	*

Dated: August 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 98N-0520]

Medical Devices; Establishment Registration and Device Listing for Manufacturers and Distributors of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain regulations governing establishment registration and device listing by domestic distributors. These amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedures for notice and comment, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws the direct final rule.

DATES: The regulation is effective February 11, 1999. Submit written comments on or before December 14, 1998. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If FDA receives any significant adverse comment, FDA intends to withdraw this final rule by publication of a document in the **Federal Register** within 30 days after the comment period ends. These provisions of FDAMA became effective on February 19, 1998.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Walter W. Morgenstern, Center for

Devices and Radiological Health (HFZ-305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20857, 301-594-4699.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105-115). Section 213(b) of FDAMA made the following changes to section 510(g) of the act (21 U.S.C. 360(g)) regarding domestic distributor registration and device listing:

1. FDAMA amended section 510(g) of the act to add a new paragraph (g)(4) to provide that the registration and listing requirements of section 510 of the act do not apply to distributors who act as "wholesale distributor," and who do not manufacture, repackaging, process, or relabel a device.

2. FDAMA also added a definition of "wholesale distributor" to section 510(g) of the act. A "wholesale distributor" is defined as "any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user."

Section 213 of FDAMA became effective on February 19, 1998, and FDA is implementing the statute as of that date. FDA is issuing this direct final rule to amend certain existing regulations to conform to amendments made by FDAMA to section 510(g) of the act.

II. Amendment Highlights

Section 807.3 (21 CFR 807.3) has been amended to incorporate the new definitions of distributor and wholesale distributor provided in amended section 510(g) of the act.

FDA is also amending § 807.3(g) to add a definition for "initial importer," because "initial importer" is excluded from the definition of wholesale distributor established by FDAMA.

Sections 807.20 and 807.22 (21 CFR 807.20 and 807.22) have been amended to implement the changes made by FDAMA to section 510(g) of the act. These amendments to 21 CFR part 807 exempt distributors of domestic or imported devices from the requirement of establishment registration and device listing. Section 807.20 is further amended to clarify that initial importers of devices continue to be subject to registration and listing.

Sections 807.3, 807.20, and 807.22 have been amended to conform the activities requiring registration with the changes made by FDAMA. Prior to FDAMA, all distributors were required to register and list. Amended section

510(g) of the act exempts wholesale distributors from registration and listing and defines a "wholesale distributor" as any person, other than the manufacturer or initial importer, who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user. The amendments to §§ 807.3, 807.20, and 807.22 reflect the changes made by FDAMA.

III. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described when and how it will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as making noncontroversial amendments to an existing regulation. The rule incorporates amendments to section 510(g) of the act made by FDAMA and FDA anticipates no significant adverse comment. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing, elsewhere in this issue of the **Federal Register**, a companion proposed rule to amend certain existing regulations governing establishment registration and device listing by domestic distributors. The companion proposed rule is substantively identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for the direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding the direct final rule.

FDA is providing a comment period on the direct final rule of December 14, 1998. If the agency receives any significant adverse comment, FDA intends to withdraw this final rule by publication of a document in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment