

drug regulations where these subject drug products and use combinations are listed. That proposed rule contains background information about those regulations and also for this action.

**DATES:** Submit written appearances and a request for a hearing by September 8, 2003. Submit all data and analysis upon which a request for a hearing relies by October 7, 2003. Submit supplemental NADAs by November 6, 2003.

**ADDRESSES:** Written requests for a hearing, data and analysis, and other written appearances are to be identified with Docket No. 2003N-0324 and submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit supplemental new animal drug applications to the Director, Office of New Animal Drug Evaluation, c/o Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

**FOR FURTHER INFORMATION CONTACT:** Andrew J. Beaulieu, Center for Veterinary Medicine (HFV-1), 7519 Standish Pl., Rockville, MD 20855, 301-827-2954, e-mail: [abeaulie@cvm.fda.gov](mailto:abeaulie@cvm.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In 1962, Congress amended the new drug provisions, which then applied to new drugs intended for both man and other animals, to require that a new drug be shown to be both safe and effective before marketing (the Drug Amendments of 1962, Public Law 87-781, 76 Stat. 780). Before 1962, animal drug approvals did not require a demonstration of effectiveness. Under the 1962 amendments, the effectiveness requirement was made applicable, after

a 2-year transition period, to animal drugs approved before 1962. This pre-1962 drug evaluation is known as the Drug Efficacy Study Implementation (DESI) program. In response to the need for an integrated approach, the DESI program evaluated the efficacy of all animal drug products, including antibiotic new animal drugs used in feed and antibiotic feed use combinations (see, e.g., § 558.15(b)(3) (21 CFR 558.15(b)(3)) and 37 FR 21279 (October 7, 1972)). Under the DESI program, a new animal drug approved before October 10, 1962, could continue to be approved if the sponsor submitted a supplemental NADA to revise the indications for use to those for which the agency determined the drug to be effective.

This document announces the effective indications for which certain new animal drugs and drug combinations may be marketed, and provides an opportunity for hearing on those indications for which products may not be marketed because they lack substantial evidence of effectiveness. There are nine products subject to this notice, and they fall into the following four categories:

1. Bacitracin methylene disalicylate (BMD) single-ingredient Type A medicated article,
2. Oxytetracycline and neomycin fixed-combination Type A medicated articles,
3. Combination drug Type B and Type C medicated feeds for poultry containing nicarbazine, and
4. Combination drug Type B and Type C medicated feeds for poultry containing bacitracin.

Under section 108(b)(2) of Public Law 90-399 (82 Stat. 353), the Animal Drug Amendments of 1968, any approval of a new animal drug granted prior to the law's effective date, whether through

approval of a new drug application, master file, antibiotic regulation, or food additive regulation, continues in effect and is subject to change in accordance with the provisions of section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b). The nine products that are the subject of this notice are subject to this transitional approval provision.

In addition, they are all listed in the interim marketing provisions of § 558.15. A history of the interim marketing provisions and the approval status of the products listed in them is contained in a notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. The agency has DESI finalized many of the products subject to the listings in § 558.15, codifying their approvals in part 558 (21 CFR part 558) subpart B (see, e.g., 61 FR 35949, July 9, 1996). The nine products subject to this notice are the only ones listed in § 558.15 that are subject to DESI and that have not yet been DESI finalized.

##### II. Findings of Effectiveness of Certain Drugs Listed in § 558.15

###### *A. Bacitracin Methylene Disalicylate Single-Ingredient Type A Medicated Articles*

The following drug is covered by the DESI findings of effectiveness for BMD in animal feed:

- NADA 141-137, FORTRACIN MD 50 (BMD) Type A medicated article used to make Type B and Type C medicated feeds. Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137.

In 1970, FDA announced its DESI findings of effectiveness for feed use of BMD (35 FR 11531, July 17, 1970, as corrected by 35 FR 15408, October 2, 1970). Table 1 of this document summarizes FDA's conclusions.

TABLE 1.—DESI FINDINGS OF EFFECTIVENESS FOR USE OF BACITRACIN METHYLENE DISALICYLATE IN ANIMAL FEED

Bacitracin methylene disalicylate in grams per ton (g/ton)	Indications for use	Limitations
4 to 50	Chickens, turkeys, and pheasants: For increased rate of weight gain and improved feed efficiency.	
5 to 20	Quail not over 5 weeks of age: For increased rate of weight gain and improved feed efficiency.	

The agency notes that there are several potential sources of confusion regarding NADA 141-137 and the interim marketing provision for BMD in § 558.15(g)(1) (further information about this provision is contained in a notice of proposed rulemaking published

elsewhere in this issue of the **Federal Register**). Section 558.15(g)(1) contains a table that lists antibacterial Type A medicated articles that are eligible for interim marketing based on compliance with other provisions of § 558.15, and specifies the sponsors of these articles

and their approved species, use levels, and indications for use. An example of the problems with this table is that the sponsors it lists for BMD—A. L. Laboratories, Inc., and Fermenta Animal Health Co.—are outdated. These companies are predecessors in interest