ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 8, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medicated Feed Mill License Application—21 CFR Part 515 (OMB Control Number 0910–0037)—Extension

In the **Federal Register** of November 19, 1999 (64 FR 63195), FDA published a final rule implementing the feed mill licensing provisions of the Animal Drug Availability Act of 1966 (Public Law 104–250). The rule added a new 21 CFR part 515 to provide the requirements for medicated feed mill licensing.

The rule sets forth the information to be included in medicated feed mill license applications and supplemental applications. It also sets forth the criteria for, among other things, the approval and refusal to approve a medicated feed mill license application, as well as the criteria for the revocation and/or suspension of a license.

Respondents to this collection of information are individuals or firms that manufacture medicated animal feed.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
515.10	7	1	7	0.25	1.75
515.11	100	1	100	0.25	25.00
515.23	25	1	25	0.25	6.25
515.30	0.15	1	0.15	24.00	3.60
Total Burden Hours					36.6

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	1,160	1	1,160	0.03	34.80

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated number of respondents is derived from agency data on the number of medicated feed manufacturers entering the market each year, changing ownership or address, requesting voluntary revocation of a medicated feed mill license, and those involved in revocation and/or suspension of a license. The estimate of the time required for this reporting requirement is based on the agency communication with industry.

Dated: August 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20201 Filed 8–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0324]

Certain Antibiotic New Animal Drug Products and Use Combinations Subject to Listings in the New Animal Drug Regulations; Drug Efficacy Study Implementation; Notice of Opportunity for Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of opportunity for hearing.

SUMMARY: The Food and Drug Administration (FDA) is announcing the effective conditions of use for certain drug products and use combinations in the following four categories: Bacitracin methylene disalicylate single-ingredient Type A medicated articles, oxytetracycline and neomycin fixed-combination Type A medicated articles, and combination drug Type B and Type C medicated feeds for poultry containing bacitracin. The agency is also proposing to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness, following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. For applications proposed to be withdrawn, the agency is providing an opportunity for hearing. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to remove certain obsolete or redundant sections of the new animal

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*.

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 nicarbazin, 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

to the current sponsors, which are Alpharma, Inc., and Pennfield Oil Co., respectively.

A second, more complicated example involves BMD's approved conditions of use. Rather than listing the use levels and indications for use for which interim marketing is permitted, the table in § 558.15(g)(1) contains a reference to another section of the regulations. When the table was first published in 1976, this reference was to the uses and indications listed in 21 CFR 121.225 and 121.252 (see 41 FR 8282, February 25, 1976). These were the conditions of use for which the BMD products were approved, under the transitional approval provisions of the Animal Drug Amendments of 1968. Shortly thereafter, these uses were recodified in § 558.76 and the reference in § 558.15(g)(1) was adjusted accordingly (41 FR 10984, March 15, 1976). Since that recodification, § 558.76 has been amended numerous times to reflect the approval of supplemental applications, based on proprietary data, that were filed by sponsors other than Pennfield Oil Co. or its predecessors in interest (see, e.g., 63 FR 40824, July 31, 1998). At the time of these amendments to § 558.76, the table in § 558.15(g)(1) was not updated by removing the simple cross reference to § 558.76 and by adding in its place a correct reference or a correct listing of the uses for which interim marketing was permitted. Thus, the table is misleading unless the reader already knows the indications for which the sponsors are approved or reviews the changes made over time to §§ 558.15 and 558.76.

The confusion caused by the reference in § 558.15(g)(1) to the use levels and indications for use in § 558.76 is illustrated by, and perhaps exacerbated by, the administrative record for NADA 141–137. As happened with several other products listed in § 558.15, it became apparent in the 1990s that the administrative record for this NADA was incomplete, calling into question its approval status. This is described in more detail in the proposed rule to remove § 558.15 published elsewhere in this issue of the **Federal Register**. In 1998, to help resolve the approval status, the company that owned the product at the time, Boehringer Ingelheim Vetmedica, Inc. (BIVI), certified that the product was approved pre-1968 and provided supporting information. This certification was made by a letter dated September 18, 1998, as amended by a letter dated November 17, 1998. It provided historical information about the product, stated that the product had been approved prior to 1968, and stated that it was subject to the transitional approval provisions of the Animal Drug Amendments of 1968. The company also provided information about the approved indications. One piece of information, included with the September letter, is a product label dated February 1969. BIVI stated that this label is consistent with § 558.15. This was probably intended to mean the interim marketing table in § 558.15 as it was originally issued in 1976 since the label's indications are generally consistent with, albeit somewhat narrower than, BMD's indications listed in the table at the time. Given this consistency and given that the date of the label is just a few months before the effective date of the transitional approval provision, the label provides good evidence that the product was subject to transitional approval and the indications for which it was transitionally approved.

However, two other pieces of information appear to be inconsistent with the indications for which FDA believes Pennfield Oil Co.'s BMD product is transitionally approved. The November 1998 letter from BIVI states that the product was approved for ''the indications for use itemized in 21 CFR § 558.78,'' which was presumably meant to be § 558.76 since the other regulation (§ 558.78) concerns bacitracin zinc. It is unclear whether BIVI meant the indications in § 558.76 in 1976 or 1998. Also unclear is the meaning of two labels faxed by BIVI to FDA on December 9, 1998. These are in the product's current NADA file, although without any cover page or other explanatory notes. These labels, one a subset of the other, specify indications that are much closer to those listed in § 558.76 in 1998 than to those that were transitionally-approved. It is possible that the labels BIVI faxed to FDA on December 9, 1998, were based on § 558.76 as it existed at that time, given that the BMD listing in § 558.15 contained the misleading cross-reference to § 558.76.

On December 17, 1998, FDA sent BIVI a letter stating that the agency received the company's November certification that amended the September letter, that the certification would be used as part of the administrative record of approval, and that the agency planned to codify this approval as soon as possible given resource constraints and public health priorities. FDA's letter also referred to the indications ''specified in the labeling attached to [BIVI's] letter.'' However, FDA's letter does not state to which labeling it is referring.

We are not aware of any additional approved indications beyond those listed in the original § 558.76 from 1976 for Pennfield Oil Co.'s product. If the sponsor has additional information on the other approved indications, such information should be provided to FDA during this administrative process.

B. Oxytetracycline and Neomycin Fixed-Combination Type A Medicated Articles

The agency is making findings of effectiveness for oxytetracycline and neomycin fixed-combination Type A medicated articles for use in animal feed. These findings cover the following drugs:

- NADA 94–975, NEO–TERRAMYCIN (oxytetracycline and neomycin). Phibro Animal Health, 710 Route 46 East, suite 401, Fairfield, NJ 07004.
- NADA 138–939, NEO–OXY (oxytetracycline and neomycin). Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137.

Both of these products are two-way, fixed-combination Type A medicated articles used to make two-way combination drug Type C medicated feeds at use levels for the species and indications listed in § 558.15(g)(2). The drug sponsor information in this listing is outdated, however, designating Pfizer, Inc., Pennfield Oil Co., and VPO, Inc., instead of Phibro Animal Health and Pennfield Oil Co.

The National Academy of Sciences/National Research Council (NAS/NRC) assisted FDA in its DESI program for numerous animal drug products. While NAS/NRC did not evaluate the efficacy data relating to these combinations, FDA has conducted such a review. This review was based on the agency's findings of effectiveness for oxytetracycline and neomycin single-ingredient feed use products, which in turn were based on NAS/NRC's evaluation (see 35 FR 7089, May 5, 1970, and 36 FR 837, January 19, 1971). FDA has determined that its previous findings of effectiveness for the single ingredients are applicable to the combinations in the absence of information indicating interference in effectiveness between individual ingredients. The agency's review also considered information about the effectiveness submitted to these two NADAs, although this information did not alter the agency's conclusions based on the single-ingredient findings. Tables 2, 3, 4, and 5 of this document summarize FDA's findings of effectiveness for oxytetracycline and neomycin fixed-combination Type A medicated articles for use in animal feed.

TABLE 2.—DESI FINDINGS OF EFFECTIVENESS FOR USE OF OXYTETRACYCLINE AND NEOMYCIN ADMINISTERED IN CHICKEN FEED IN A 1:1 RATIO

Oxytetracycline and neomycin amount in g/ton of feed	Indications for use	Limitations
10 to 50	Chickens: For increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.
100 to 200	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days (d); do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter.
400	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.
500	Chickens: For reduction of mortality due to air sacculitis (air-sac- infection) caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter.

TABLE 3.—DESI FINDINGS OF EFFECTIVENESS FOR USE OF OXYTETRACYCLINE AND NEOMYCIN ADMINISTERED IN TURKEY FEED IN A 1:1 RATIO

Oxytetracycline and neomycin amount	Indications for use	Limitations
10 to 50 g/ton of feed	Growing turkeys: For increased rate of weight and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.
100 g/ton of feed	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.
200 g/ton of feed	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.
25 milligrams per pound (mg/lb) of body weight daily	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.

TABLE 4.—DESI FINDINGS OF EFFECTIVENESS FOR USE OF OXYTETRACYCLINE AND NEOMYCIN ADMINISTERED IN SWINE FEED IN A 1:1 RATIO

Oxytetracycline and neomycin amount	Indications for use	Limitations
10 to 50 g/ton of feed	Swine: For increased rate of weight and improved feed efficiency	
10 mg/lb of body weight daily	Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.
10 mg/lb of body weight daily	Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for not more than 14 d; withdraw 5 d before slaughter.

TABLE 5.—DESI FINDINGS OF EFFECTIVENESS FOR USE OF OXYTETRACYCLINE AND NEOMYCIN ADMINISTERED IN CATTLE AND SHEEP FEED IN A 1:1 RATIO

Oxytetracycline and neomycin amount	Indications for use	Limitations
10 to 20 g/ton of feed	Sheep: For increased rate of weight gain and improved feed efficiency.	
0.05 to 0.1 mg/lb of body weight daily	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency.	Feed continuously; in milk replacers or starter feed.
10 mg/lb of body weight daily	Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d in feed or milk replacers. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.
10 mg/lb of body weight daily	Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d in milk replacers or starter feed. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.
10 mg/lb of body weight daily	Sheep: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter.
25 mg/head/d	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency.	
75 mg/head/d	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	
0.5 to 2.0 g/head/d	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazin

The agency is making findings of effectiveness for combination drug Type B and Type C medicated feeds containing nicarbazin. These findings cover the following drugs:

• NADA 98–371, for the combination use of NICARBAZIN (nicarbazin), PENICILLIN G PROCAINE (procaine penicillin), and 3–NITRO (roxarsone). Phibro Animal Health.

• NADA 98–374, for the combination use of NICARBAZIN (nicarbazin) and PENICILLIN G PROCAINE (procaine penicillin). Phibro Animal Health.

• NADA 100–853, for the combination use of NICARBAZIN (nicarbazin), BACIFERM (BMD), and 3–NITRO (roxarsone). Phibro Animal Health.

These three combination drugs are for uses listed in § 558.15(g)(2). The drug sponsor information in the listing is outdated, designating The Upjohn Co. instead of Phibro Animal Health. In addition, rather than itemizing the indications for use, the listing gives references to the indications itemized in §§ 558.325, 558.355, and 558.530. These references are not accurate since they are for lincomycin, monensin, and roxarsone.

While NAS/NRC did not evaluate the efficacy data relating to these combinations, FDA has conducted such a review. This review was based on the agency's findings of effectiveness for bacitracin zinc, nicarbazin, procaine penicillin, and roxarsone single-ingredient feed use products, which in turn were based on NAS/NRC's evaluation (see 35 FR 12490, August 5, 1970 (bacitracin zinc); 34 FR 6495, April 15, 1969 (nicarbazin); 35 FR 11534, July 17, 1970 (procaine penicillin); and 35 FR 14273, September 10, 1970 (roxarsone)). FDA has determined that its previous findings of effectiveness are applicable to the combinations in the absence of information indicating interference in effectiveness between individual ingredients. Table 6 of this

document summarizes FDA's findings of effectiveness for certain combination drug Type B and Type C medicated feeds containing nicarbazin.

TABLE 6.—FINDINGS OF EFFECTIVENESS FOR USE OF CERTAIN DRUG COMBINATIONS CONTAINING NICARBAZIN IN POULTRY FEED

Type A article in g/ton	Type A article in g/ton	Type A article in g/ton	Indications for use	Limitations
Nicarbazin 90.8 to 181.6 (0.01 to 0.02 percent (pct)	Bacitracin methylene disalicylate 4 to 50	Roxarsone 22.7 to 45.4	Growing chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. As a sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Do not use in flushing mashes. Do not feed to laying hens in production. Discontinue medication 5 d before marketing the birds for human consumption to allow for elimination of the drug from edible tissue.
Nicarbazin 90.8 to 181.6 (0.01 to 0.02 pct)	Procaine penicillin 2.4 to 50		Growing chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to chickens producing eggs for human consumption. Discontinue medication 4 d before marketing the birds for human consumption to allow for elimination of the drug from edible tissue.
Nicarbazin 90.8 to 181.6 (0.01 to 0.02 pct)	Procaine penicillin 2.4 to 50	Roxarsone 22.7 to 45.4	Growing chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. As a sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Do not use in flushing mashes. Do not feed to chickens producing eggs for human consumption. Discontinue medication 5 d before marketing the birds for human consumption to allow for elimination of the drug from edible tissue.

D. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Bacitracin

The agency is making findings of effectiveness for combination drug Type B and Type C medicated feeds containing bacitracin. These findings cover the following drugs:

- NADA 141–130, for the combination use of BMD and zoalene. Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024.
- NADA 141–131, for the combination use of BMD, zoalene, and roxarsone. Alpharma, Inc.
- NADA 141–132, for the combination use of zinc bacitracin and nitarsone. Alpharma, Inc.

These three combination drugs are for uses listed in § 558.15(g)(2). The drug sponsor information in the listing is outdated, designating A. L. Laboratories, Inc., instead of Alpharma, Inc.

While NAS/NRC did not evaluate the efficacy data relating to these combinations, FDA has conducted such a review. This review was based on the agency's findings of effectiveness for BMD, bacitracin zinc, nitarsone, roxarsone, and zoalene single-ingredient feed use products. Most of these were based on NAS/NRC's evaluation (see 35 FR 11531, July 17, 1970 (BMD); 35 FR 12490, August 5, 1970 (bacitracin zinc); 34 FR 6494, April 15, 1969 (nitarsone); and 35 FR 14273, September 10, 1970 (roxarsone)). The effectiveness of zoalene in these combinations was based on FDA's review of a food additive petition containing effectiveness data (see 27 FR 11546, November 24, 1962). FDA has determined that its previous findings of effectiveness are applicable to the combinations in the absence of information indicating interference in effectiveness between individual ingredients. Table 7 of this document summarizes FDA's findings of effectiveness for certain combination drug Type B and Type C medicated feeds containing bacitracin.

TABLE 7.—FINDINGS OF EFFECTIVENESS FOR USE OF CERTAIN DRUG COMBINATIONS CONTAINING BACITRACIN IN POULTRY FEED

Type A article in g/ton	Type A article in g/ton	Type A article in g/ton	Indications for use	Limitations
Bacitracin 4 to 50	Zoalene 36.3 to 113.5.		Replacement chickens: For increased rate of weight gain and improved feed efficiency; and for development of active immunity to coccidiosis.	As bacitracin methylene disalicylate. Grower ration not to be fed to birds over 14 weeks of age; feed as in § 558.680(d)(1)(i).
Bacitracin 4 to 50	Zoalene 36.3 to 113.5.	Roxarsone 22.7 to 45.4	Replacement chickens: For increased rate of weight gain and improved feed efficiency; for development of active immunity to coccidiosis; and for improved pigmentation.	As bacitracin methylene disalicylate; discontinue use 5 d before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Grower ration not to be fed to birds over 14 weeks of age; feed as in § 558.680(d)(1)(i).
Bacitracin 4 to 50	Nitarsone 170 (0.01875 pct)		Growing turkeys: For increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of blackhead.	As bacitracin zinc; discontinue use 5 d before slaughter. Early medication is essential to prevent spread of disease. Adequate drinking water must be provided near feeder at all times. The drug is not effective in preventing blackhead in birds infected more than 4 or 5 d. The drug is dangerous for ducks, geese, and dogs. Overdosage or lack of water may result in leg weakness or paralysis. Use as sole source of arsenic.

E. Applicability of Findings of Effectiveness

The findings of effectiveness as described previously in this document are concerned only with a drug's effectiveness for the stated conditions in the treated animals. Nothing in this document constitutes a bar to further proceedings with respect to questions of the safety of the subject drugs in treated animals or of the drugs or their metabolites in food products derived from treated animals.

F. Applicability of Pending Notices of Opportunity for Hearing

In the **Federal Registers** of August 30, 1977 (42 FR 43772), and October 21, 1977 (42 FR 56264), the Director of the Center for Veterinary Medicine (CVM) issued notices of opportunity for

hearing (NOOHs) on proposals to withdraw approval of NADAs for all penicillin-containing premix products intended for use in animal feed and for certain subtherapeutic uses of tetracyclines (chlortetracycline and oxytetracycline) in animal feed. Some of these products are listed in § 558.15. These NOOHs are still pending and nothing in this document constitutes a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOHs.

G. Marketing

Marketing of the products that are the subject of this document, and which are approved, may be continued, provided that, on or before (see **DATES**), the holder of the application submits a signed Form FDA 356v *New Animal Drug Application* and complete product labeling (including specimen labeling for Type B and Type C medicated feeds) conforming to the applicable findings of effectiveness.

Supplemental NADAs that are filed in response to this document and comply with the requirements set forth will be approved, and documents will be published in the **Federal Register** amending the approval regulations in accordance with the approval and identifying the sponsor under section 512(i) of the act.

III. Notice of Opportunity for Hearing

On the basis of all available data and information, the Director of CVM is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 512 of the act that demonstrates effectiveness of the drugs listed in section II of this document, for their labeled indications of use other than the effective claims as stated in this document.

Therefore, notice is given to the sponsors of the NADAs for the nine animal drug products or combination uses described in section II of this document, and to all other interested persons, that the Director of CVM proposes to issue an order under section 512(e) of the act withdrawing approval of the NADAs providing for any claims other than those classified in this document as effective. The ground for the proposed withdrawal is that new information about the drug products, such as that provided by the NAS/NRC reviews, evaluated together with the evidence available at the time of approval, show there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. An order withdrawing approval will not issue with respect to any application supplemented in accordance with this document to delete any indication for use lacking substantial evidence of effectiveness.

This notice of opportunity for hearing encompasses, in addition to the ground for the proposed withdrawal of the approvals, all issues relating to the legal status of the drug products subject to it, e.g., any contention that any such product is not a new animal drug within the meaning of section 201(w) of the act (21 U.S.C. 321(w)).

In accordance with section 512 of the act and part 514 (21 CFR part 514) and under the authority delegated to the Director of CVM (21 CFR 5.502), a sponsor and all other persons subject to this document are hereby given an opportunity for hearing to show why approval of the applications should not be withdrawn.

A sponsor or any other person subject to this document who wishes to request a hearing must file: (1) On or before (see **DATES**), a written notice of appearance and request for a hearing, and (2) on or before (see **DATES**), the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact to justify a hearing as specified in § 514.200. Any other interested person may also submit comments on this document. Procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of a hearing, are contained in § 514.200 and 21 CFR part 12.

The failure of a holder of an approval, or any other party subject to this document, to file a timely written appearance and request for hearing as required by § 514.200 constitutes an election not to avail itself of the opportunity for hearing and a waiver of any contentions concerning the legal status of any such drug product, and the Director of CVM will summarily enter a final order withdrawing the approval. Any such drug product labeled other than for the effective claims identified in this document may not thereafter be marketed lawfully, and FDA will initiate appropriate regulatory action to remove any such drug product from the market. Any new animal drug product marketed without an approved NADA is subject to regulatory action at any time.

A request for hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests a hearing, making findings and conclusions, and denying a hearing.

If a hearing is requested and is justified by the sponsor's response to this notice of opportunity for hearing, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

All submissions under this document must be filed in four copies. Except for data and information prohibited from public disclosure by law, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m. Monday through Friday. This document is issued under section 512 of the act and under the authority delegated to the Director of CVM (21 CFR 5.502).

IV. Environmental Impact

The agency has determined under 21 CFR 25.33(g) 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.

V. Paperwork Reduction Act of 1995

The collections of information requirements for this document are covered under OMB control numbers 0910–0032 and 0910–0184.

Dated: August 1, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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