

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. AlphaPharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024.

- NADA 141-131, for the combination use of BMD, zoalene, and roxarsone. AlphaPharma, Inc.

- NADA 141-132, for the combination use of zinc bacitracin and nitarosone. AlphaPharma, 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 The drug sponsor information in the listing is outdated, designating A. L. Laboratories, Inc., instead of AlphaPharma, Inc.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, nitarosone, 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 (nitarosone); 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	Nitarosone 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