Approval Date: May 27, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 065-470

B. Sponsor

Alpharma, Inc.
One Executive Drive
Fort Lee, New Jersey 07024

C. Proprietary Name

BMD Soluble

D. Established Name

Bacitracin methylene disalicylate

E. Dosage Form

BMD® Soluble is available in foil packets weighing 4.1 oz (116.2 g). Each packet of soluble powder contains 51.2 g bacitracin activity from bacitracin methylene disalicylate equivalent to 200 g bacitracin activity per pound or to 18,520 units bacitracin (master standard) per gram.

F. Dispensing Status

OTC

G. Route of Administration

Oral, via drinking water

H. Indication

BMD® Soluble (bacitracin methylene disalicylate soluble powder) is indicated for the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.

I. Effect of Supplement

This supplemental application provides for the addition of an additional species, growing quail, to the previously approved product.

II. EFFECTIVENESS

The effectiveness of 200 g bacitracin methylene disalicylate/ton of feed for the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate was demonstrated in a supplemental application to NADA 046-592 which was approved on February17,1989. It has been established in NADA 046-592 and NADA 065-470 that *x* grams of bacitracin methylene disalicylate/ton of feed is approximately

equivalent to *2x* mg bacitracin methylene disalicylate/gallon of water (e.g.,400mg/gal is equivalent to approximately 200 g of feed grade BMD/ton of feed). As the effectiveness of 200 g bacitracin methylene disalicylate per ton of feed for the prevention of ulcerative enteritis in growing quail has been established in the approved supplement to NADA 046-592, additional effectiveness studies were not required for this supplemental application.

III. TARGET ANIMAL SAFETY

Bacitracin methylene disalicylate was approved on February 17, 1989, (NADA 046-592) for use in the feed of growing quail for the prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate. Based on the margin of safety (10X the recommended dosage) previously documented in the safety studies summarized for use of this drug in quail feed, additional safety studies were not required for this supplemental application.

IV. HUMAN FOOD SAFETY

The tolerance for residues of bacitracin in edible uncooked tissues of chickens, turkeys, and quail has been established as 0.5 ppm under 21 CFR 556.70.

Soluble bacitracin methylene disalicylate is approved for chickens and turkeys at dosage levels up to 400 mg/gal of drinking water. No withdrawal period is required. The proposed 400 mg/gal level in quail is restricted to growing birds.

No residues above the tolerance have been observed either at 400 mg/gal use level or at 2000 mg/gal level when given to chickens or turkeys. Based on this experience, residues above the tolerance would not be expected in quail, a related species, when added to the drinking water at 400 mg/gal. Consequently, residue studies at this dose level were not required for quail, a minor species.

V. AGENCY CONCLUSIONS

The data submitted in support of this NADA supplement satisfy the requirements of Section 512 of the Federal Food, Drug and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that bacitracin methylene disalicylate, when administered continuously in the drinking water of growing quail at a concentration of 400mg/gallon, is safe and effective for the prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.

The tolerance for residues of bacitracin in edible uncooked tissues of chickens, turkeys, and quail has been established as 0.5 ppm under 21 CFR 556.70. Soluble bacitracin methylene disalicylate is approved for chickens and turkeys at dosage levels up to 400 mg/gal of drinking water, and no withdrawal period is required. No residues above the tolerance have been observed either at 400 mg/gal use level or at 2000 mg/gal level when given to chickens or turkeys. Based on this experience, residues above the tolerance would not be expected in quail, a related species, when added to the drinking water at 400 mg/gal.

Proper use by lay persons can be expected because the directions are clearly written and there is reasonable certainty that the conditions of use, including

mixing directions on the label, can and will be followed by the producer. The agency has concluded that this product can be approved for over-the-counter use.

The agency has determined under 21 CFR 25.33(d)(4) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), these are Category II changes. The approval of these changes is not expected to have any adverse effect on the safety or effectiveness of this new animal drug and, therefore, did not require a reevaluation of the human food or target animal safety data in the parent application.

VI. ATTACHMENTS

BMD® Soluble Foil Packet Label
BMD® Soluble Shipper Label
Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.