Approval Date: September 1, 1994

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 128-686

B. Sponsor

Agri-Bio Corporation
P.O. Box 897 Gainesville
Georgia 30503

C. Proprietary Name

Bio-Cox®

D. Established Name

salinomycin sodium

E. Dosage Form

Type A medicated article to be mixed with feed to produce a Type C medicated feed.

F. Dispensing Status

OTC

G. Dosage Regimen

Broiler chickens:	40 to 60 g/ton of Type C medicated feed
Quail:	50 g/ton of Type C medicated feed

H. Route of Administration

This drug is administered orally by adding the Type A medicated article.

I. Indication

Broiler chickens:	For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.
Quail:	Prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*.

II. EFFECTIVENESS

Efficacy data from the FOI summary for PMF 5020, 54 FR 11569, March 21, 1989, demonstrated that a level of 50 g/ton (0.0055%) salinomycin sodium in complete feed was efficacious based on weight gain and reduction of parasite numbers for the prevention of coccidiosis caused by Eimeria lettyae and E. dispersa in quail.

III. TARGET ANIMAL SAFETY

Target animal safety data from the FOI summary for PMF 5020, 54 FR 11569. March 21, 1989, demonstrated that administration of salinomycin sodium in feed at 2 times the recommended dose for 28 consecutive days is safe and nontoxic to quail.

IV. HUMAN FOOD SAFETY

Toxicity Testing:

These have been adequately addressed in the FOI summary for PMF 5020.

Safe Concentration:

The safe concentrations for total salinomycin residues in uncooked edible tissues of broiler chickens were established at 0.6 ppm in muscle, 1.8 ppm in liver, and 1.2 ppm in skin/fat (48 FR 30616, July 5, 1983). An upper limit of unchanged salinomycin in skin/fat is established at 200 ppb.

Withdrawal Time:

Residue depletion data submitted under PMF 5020, 54 FR 11569, March 21, 1989, support a zero day withdrawal period for daily feeding of 50 g/ton (0.0055%) salinomycin sodium to quail.

V. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Act and demonstrate that salinomycin sodium, when used under the proposed conditions of use, is safe and effective for the prevention of coccidiosis caused by Eimeria lettyae and E. dispersa in quail.

Based on tissue residue studies, a zero day slaughter period is assigned for quail treated with salinomycin sodium at the recommended dosage.

The original approval of salinomycin sodium was as an over-the-counter drug. Accurate diagnosis of coccidiosis in quail, which is the new species to be added to the label, can be made with reasonable degree of certainty by the layman.

Adequate directions for use have been written for the layman, and the conditions for use prescribed on the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product shall have over-the-counter marketing status.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a Category II change. The approval of this change did not require a reevaluation of the safety or effectiveness data in the parent application.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

VI. REFERENCES

This FREEDOM OF INFORMATION SUMMARY references data in Public Master File (PMF) 5020, 54 FR 11569, March 21, 1989, in support of the supplemental new animal drug application. The data were generated by:

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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.