Approval Date: March 18, 1994

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number
ANADA 200-083

B. Sponsor
Hoechst-Roussel Agri-Vet Company
P.O. Box 2500
Somerville, New Jersey 08876-1258

C. Proprietary Name
Sacox, Flavomycin

D. Established Name
salinomycin sodium, bambermycins

E. Dosage Form
Type A medicated articles

F. Lable Claim of Amount of Active Ingredient(s)
Salinomycin sodium: 30 g/lb of Type A medicated article
Bambermycins: 2, 4, and 10 g/lb of Type A medicated article

G. Route of Administration
These drugs are administered orally by adding the Type A medicated articles to complete broiler feed (Type C medicated feed).

H. How Supplied
Salinomycin sodium: 50-lb bags
Bambermycins: 50-lb bags

I. Dispensing Status
OTC

J. Labeled Dosage
Salinomycin sodium: 40 to 60 g/ton (0.0044-0.0066%)
Bambermycins: 1 to 3 g/ton (0.00011-0.00033%)

K. Species/Class
Broiler chickens

L. Indication

For the prevention of coccidiosis in broiler chickens caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti* and *E. mivati* , and for improved feed efficiency.

M. Reference Listed New Animal Drug

Bio-Cox
Salinomycin sodium
NADA 128-686
Agri-Bio Corporation

Flavomycin
NADA 44-759
Hoechst-Roussel Agri-Vet Company

Bio-Cox/Flavomycin
Salinomycin sodium/Bambermycins
NADA 134-284
Agri-Bio Corporation

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

In accordance with the Center's policy letter dated November 2, 1989, as published in the Federal Register on January 30, 1990 (55 FR 3107), following the approval of an ANADA for a generic Type A medicated article (ANADA 200-075; generic salinomycin sodium), Hoechst-Roussel Agri-Vet Company is entitled to the approval of generic salinomycin in combination with bambermycins. Bioequivalence studies are not required for the approval of this generic combination (Type C medicated feed). Salinomycin sodium is codified under 21 CFR § 558.550. Bambermycins is codified under 21 CFR § 558.95. The combination of salinomycin sodium and bambermycins is codified under 21 CFR § 558.95Co)(1)(xii).

III. HUMAN FOOD SAFETY

In accordance with the Centers policy letter dated November 2, 1989, as published in the Federal Register on January 30, 1990 (55 FR 3107), tissue residue studies are not required for the approval of this generic combination (Type C medicated feed).

A. Tolerances for Residues

The tolerance established for the pioneer salinomycin sodium product applies to the generic salinomycin sodium product. The safe concentrations for total salinomycin residues in the uncooked edible tissues of broiler chickens were established as 0.6 ppm in muscle, 1.8 ppm in liver, and 1.2 ppm in skin/fat.

Bambermycins has a no-tolerance clearance as published in 40 FR 59726 (December 30, 1975). The safe concentration for total bambermycins residues in the uncooked edible tissues of broiler chickens were established in NADA 44-759 (38 FR 1274; January 11, 1973).

B. Withdrawal Time

Based on the information in 21 CFR § 558.95(b)(1)(xii), a 0-day withdrawal time is required for the combination ofbambermycins and salinomycin.

C. Regulatory Method for Residues

A regulatory method for salinomycin was not required because residue levels in all three broiler tissues (muscle, liver, and skin/fat) were significantly below the established safe concentration for total residues.

A microbiological assay method is used to assay tissues for bambermycins residues. The method entitled "Quantitative Agar Well Plate Assay of Bambermycins (Flavomycin) in Organs and Tissues" is on file at the Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

IV. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that the combination of salinomycin sodium and bambermycins when used under its proposed conditions of use, is safe and effective for its labeled indications.

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.