

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-210

B. Sponsor

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

C. Proprietary Name

Sacox[®], Albac[®]

D. Established Name

salinomycin, bacitracin zinc

E. Dosage Form

Type A medicated articles

NOTE: This ANADA provides for the combined use of two approved Type A medicated articles (SACOX[®] and ALBAC[®] in Type C medicated feeds, rather than a premix incorporating both of these compounds.

F. Amount of Active Ingredient

Salinomycin: 30 or 60 g/lb of salinomycin in Type A medicated article
Bacitracin zinc: 50 g/lb bacitracin zinc in Type A medicated article

G. How Supplied

Salinomycin: 50-lb bags
Bacitracin zinc: 50-lb bags

H. Dispensing Status

OTC

I. Route of Administration

These drugs are administered orally by adding the Type A medicated articles to complete chicken feed (Type C medicated feed).

J. Labeled Dosage:

Salinomycin: 40 to 60 g/ton
Bacitracin Zinc: 10 to 50 g/ton

K. Species/Class

Broiler chickens

L. Indication

For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mivati*, and for increased rate of weight gain.

M. Feeding Directions

Feed continuously as the sole ration.

N. Label Cautions

Do not feed to laying chickens. Not for use in feeds for breeder chickens. May be fatal if fed to adult turkeys or to horses. Not approved for use with pellet binders.

O. Generic Product

ALBAC®
Bacitracin zinc
ANADA 200-223
ALPHARMA, Inc.

P. Pioneer Product/"Listed" Product

BACIFERM®
Bacitracin zinc
NADA 46-920
Hoffmann-La Roche, Inc.

SACOX®
Salinomycin
ANADA 200-075
Hoechst-Roussel Vet

SACOX®/BACIFERM®
Salinomycin/bacitracin zinc
ANADA 200-089
Hoechst-Roussel Vet

II. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

In accordance with the Center for Veterinary Medicine'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 200-223, generic bacitracin zinc), ALPHARMA, Inc., is entitled to the approval of generic bacitracin zinc in combination with salinomycin. Bioequivalence studies are not required for the approval of this generic combination (Type C medicated feed). Bacitracin zinc is codified under 21 CFR §558.78. Salinomycin is codified under 21 CFR §558.550. The combination of bacitracin zinc and salinomycin is codified under 21 CFR §558.550 (b)(1)(vii).

III. HUMAN FOOD SAFETY

A. Tolerances for the Marker Residue

The tolerances established for the pioneer bacitracin zinc product apply to the generic bacitracin zinc product.

The tolerances for residues of bacitracin from bacitracin zinc are established at 0.5 ppm (0.02 unit per gram), negligible residue, in uncooked edible tissues of chickens (21 CFR §556.70).

Under NADA 128-686 a tolerance 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.

B. Withdrawal Time

Based on the information in 21 CFR §558.550(b)(1)(vii), a withdrawal time is not required for the use of the combination of bacitracin and salinomycin in broiler chickens.

C. Regulatory Method for Residues

The regulatory analytical method for detection of residues of bacitracin is a microbiological test using *Sarcina subflava* (ATCC 7468) or *Micrococcus subflavus* (ATCC 10240). The method is found in *Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols*, Revised October 1968, Reprinted December 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

Modified Method for the Determination of Bacitracin in Tissues, Test Procedure Code 9A, AL Laboratories, One Executive Dr. PO Box 1399, Fort Lee NJ 07024.

Under NADA 128-686 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.

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 and bacitracin zinc, 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.