Approval letter dated: November 8, 2002

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-075

Sacox®

"Addition of Roaster, Replacement (Breeder and Layer) Chickens and Quail"

Sponsored by:
Intervet Inc.
Millsboro, DE 19966

FREEDOM OF INFORMATION SUMMARY

ANADA 200-075

I. GENERAL INFORMATION

ANADA Number:	200-075
Sponsor:	Intervet Inc. 405 State Street Millsboro, DE 19966-0318
Generic Names:	salinomycin sodium
Trade Name:	Sacox®
Effect of Supplement:	To add roaster and replacement (breeder and layer) chickens to the label claim for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti* and *E. mivati*; and to add quail to the label claim for the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae.*
How Dispensed:	OTC
Amount of Active Ingredient:	Type A Medicated Article containing 60 grams salinomycin sodium per pound.
Pioneer Product:	Bio-Cox®; salinomycin sodium; NADA #128-686; Alpharma, Inc.

II. INDICATIONS FOR USE

BROILER, ROASTER, REPLACEMENT (BREEDER AND LAYER) CHICKENS

For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

QUAIL

For the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*.

III. DOSAGE

A. DOSAGE FORM	Type A medicated article to be mixed with feed to produce a Type C medicated feed.
B. ROUTE OF ADMINISTRATION	This drug is administered orally by adding Type A medicated article to feed to make complete feed (Type C medicated feed).

C. RECOMMENDED DOSAGES:

BROILER, ROASTER, REPLACEMENT (BREEDER AND LAYER) CHICKENS	40 to 60 g/ton of Type C medicated feed
QUAIL	50 g/ton of Type C medicated feed

IV. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1998, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter, Bioequivalence Guidance, October 10, 2000).

Based upon the formulation characteristics of the generic product, Sacox®, was granted a waiver dated December 28, 1992, from conducting an *in vivo* bioequivalency study. The abbreviated new animal drug application was approved on February 23, 1994.
The generic and pioneer products contain the same active but different inactive ingredients and are medicated feed products.

V. HUMAN FOOD SAFETY

a. Acceptable Daily Intake (ADI)

The ADI for total residues of salinomycin is 0.005 milligram per kilogram of body weight per day.

b. Withdrawal Time

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal period assigned to the generic product is the same as that previously assigned to the pioneer product. A zero withdrawal is established for salinomycin sodium in roaster chicken, replacement (breeder and layer) chicken and quail feed.

c. Regulatory Method

A regulatory method was not required.

VI. AGENCY CONCLUSIONS

This Supplemental Abbreviated New Animal Drug Application filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrated that Sacox® is safe and effective for its labeled indications, when used under its proposed conditions of use.

VII. ATTACHMENTS

The following generic labeling and currently approved pioneer labeling are available.

1. Package label for generic Type A medicated article – Sacox
2. Package bluebird labels for generic Type C medicated feed (chicken and quail).
3. Pioneer package label for Type A medicated article – Biocox
4. Pioneer blue bird laels for Type C medicated feed (chicken and quail).

Copies of these 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) 443-1746. If there are problems sending a fax, call (301) 827-6567.