Approval Date: September 30, 1988

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 140-847

B. Sponsor

Altana Inc.
60 Baylis Road
Melville, New York 11747

C. Proprietary Name

Animax Ointment

D. Established Name

nystatin, neomycin sulfate, thiostrepton, triamcinolone acetonide ointment

E. Dosage Form, Route of Administration and Recommended Dosage

The active ingredients are formulated in an ointment base.

Animax Ointment is indicated for topical administration.

Frequency of administration is dependent on the severity of the condition. For mild inflammations, application may range from once daily to once a week; for severe conditions Animax Ointment may be applied as often as two or three times daily, if necessary. Frequency of treatment may be decreased as improvement occurs.

Otitis: Clean ear canal of impacted cerumen. Inspect canal and remove any foreign bodies such as grass awns, ticks, etc. Instill three to five drops of Animax Ointment.

Preliminary use of a local anesthetic may be advisable.

Infected Anal Gland, Cystic Areas, etc.: Drain gland or cyst and then fill with Animax Ointment.

Other Dermatologic Disorders: Clean affected areas, removing any encrusted discharge or exudate. Apply Animax Ointment sparingly in a thin film.

F. Dispensing Status

Rx

G. Indication

Animax Ointment (nystatin, neomycin sulfate, thiostrepton, triamcinolone acetonide ointment) is particularly useful in the treatment of acute and chronic otitis of varied etiologies, in interdigital cysts in cats and dogs, and in anal gland infections in dogs.

The preparation is also indicated in the management of dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated, or threatened by bacterial or candidal (*Candida albicans*)

infections. It is also of value in eczematous dermatitis, contact dermatitis, and seborrheic dermatitis, and as an adjunct in the treatment of dermatitis due to parasitic infestation.

II. EFFECTIVENESS

Animax Ointment and the pre-1962 pioneer product (Panalog Ointment NADA 12-258, Solvay Veterinary, Inc., formerly E.R. Squibb & Sons, Inc.) contain the same active ingredients. Both products contain nystatin 100,000 units, neomycin sulfate 2.5 mg, thiostrepton 2,500 units, and triamcinolone acetonide 1.0 mg. The pioneer product, Panalog Ointment, was the subject of a review by the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group. NAS/NRC determined Panalog Ointment to be "probably effective" and recommended labeling changes. Subsequently, the product was determined to be "effective" by the Center for Veterinary Medicine (CVM) when the application was supplemented by providing the required label revisions. This was published in a Federal Register Notice, Volume 35, No. 166, Wednesday, August 26, 1970. It was also codified in 21 CFR 524.1600a.

This product is chemically equivalent to the approved product, it bears the same claims, it is topically applied and is for local therapeutic effect. Therefore, as provided under 21 CFR 320.22, the Center for Veterinary Medicine waived the requirement for submission of evidence of in vivo bioavailability and bioequivalency.

III. TARGET ANIMAL SAFETY

Reference is again made to the NAS/NRC review of Panalog Ointment. The Council determined the product was safe and "probably effective" with labeling changes. The safety of the product was increased by changing its marketing status from OTC to Rx. In addition, the Animax Ointment labeling includes the safety information required by CVM in the Federal Register announcement of December 13, 1984 covering drug products containing a steroid.

IV. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this NADA. This product is labeled as a prescription drug for use only on cats and dogs, which are non-food animals.

Human Safety Relative to Possession, Handling and Administration

Labeling contains an adequate caution statement.

Dosage and Administration section of the package insert states: "Wear gloves during the administration of the ointment or wash hands immediately after application."

V. AGENCY CONCLUSIONS

This is a generic NADA. The pre '62 pioneer prototype is Panolog (NADA 12-258). In accordance with 21 CFR 320.22, CVM waived the requirement for bioequivalency data for revisions recommended by the NAS/NRC efficacy panel and required by the Agency to establish safety and effectiveness. Approval is based on the chemical equivalency of this generic drug and the pre '62 pioneer drug.

Animax Ointment, when used under its approved conditions of use, is safe and effective for the treatment of acute and chronic otitis of varied etiologies, for interdigital cysts in cats and dogs, for anal gland infections in dogs, for management of moist or dry dermatologic disorders characterized by inflammation: bacterial, candidal (*Candida albicans*), contact, eczematous, seborrheic, and parasitic (ear mites).

The labeling for this product contains the veterinary prescription legend because the expertise of a veterinarian is necessary for diagnoses of the etiologies of the conditions for which the product is indicated, for proper preparation of the animals for drug administration (otitis & anal glands) and for supervision of the progress of the animals to reduce the potential of adverse side effects such as: SAP and SGPT (ALT) enzyme elevations, polydypsia/polyuria, vomiting, diarrhea (occasionally bloody), Cushing's syndrome, and deafness.

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