

## FREEDOM OF INFORMATION SUMMARY

### I. GENERAL INFORMATION

#### A. File Number

NADA 140-879

#### B. Sponsor

Norden Laboratories  
601 West Cornhusker Highway  
Lincoln, Nebraska 68521

#### C. Proprietary Name

DERMA 4 Ointment

#### D. Established Name

nystatin – neomycin sulfate – thiostrepton –  
triamcinolone – acetonide topical ointment

#### E. Route of Administration

topical

#### F. Indication

DERMA 4 Ointment is particularly useful in the treatment of: (1) acute and chronic otitis of varied etiologies; (2) interdigital cysts in dogs and cat; (3) anal gland infections in dogs; (4) dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated, or threatened by bacterial or candidal (*Candida albicans*) infection; and (5) eczematous, contact and seborrheic dermatitis. Additionally, DERMA 4 Ointment may be used as an adjunct in the treatment of dermatitis due to parasitic infestation.

### II. EFFECTIVENESS

DERMA 4 Ointment (nystatin, neomycin sulfate, thiostrepton, triamcinolone acetonide) is chemically identical to Panalog Ointment (NADA 12-258, Solvay Veterinary, Inc., formerly E.R. Squibb & Sons, Inc.) which was the subject of a review by the National Academy of Science/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.

The DERMA 4 Ointment labeling contains the same claims as those contained on the labeling for Panalog Ointment, the pioneer product. In addition, the DERMA 4 Ointment labeling includes the safety information required by CVM in the Federal Register announcement of December 13, 1984 covering drug products containing a steroid.

Under the policy of the Center for Veterinary Medicine, the principles of 21 CFR 320.22, providing for a waiver of the requirement for submission of evidence of in vivo bioavailability/bioequivalence, are applicable to NAS/NRC reviewed topically applied veterinary new animal drug preparations intended for local therapeutic effect. Since DERMA 4 Ointment is chemically identical to the NAS/NRC reviewed Panalog Ointment, the waiver applies to this product.

The effectiveness of this combination has been proven in over 25 years of continuous veterinary use.

### 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 over the counter (OTC) to prescription (Rx). In addition, the DERMA 4 Ointment labeling includes the safety information required by CVM in the Federal Register announcement of December 13, 1984 covering drug products containing a steroid. Likewise, the safety of this combination has been proven in over 25 years of continuous veterinary use.

### IV. HUMAN FOOD SAFETY

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

#### **Human Safety Considerations Other Than Food Safety:**

In regard to possession, handling and administration, adequate information is provided under the headings "warning", "precautions", and "side effects" on the package insert for the safe use of the product by veterinarians and to instruct their clients on its proper and safe use.

### V. AGENCY CONCLUSIONS

The data submitted in support of this NADA comply with the conclusions of the NAS/NRC review, as concurred with by FDA, and with CVM's policy concerning topical drugs. The data demonstrated that DERMA 4 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), for the administration of the drug (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, polydipsia/polyuria, vomiting, diarrhea (occasionally bloody), Cushings syndrome, and deafness.

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.