Approval Date: August 4, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-196

B. Sponsor

Med-Pharmex, Inc.
2727 Thompson Creek Rd
Pomona, CA 91767-1861

C. Proprietary Name

Miconosol

D. Established Name

miconazole nitrate lotion/spray 1%

E. Dosage Form

The product is available in the form of a lotion or spray for external application.

F. Dispensing Status

Rx

G. Routes of Administration and Dosage Regimen

Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

Apply a light covering of MICONOSOL (miconazole nitrate) Lotion/Spray 1% to affected areas, once daily, for 2 to 4 weeks. Application is best accomplished using a gauze pad or cotton swab. Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

For the spray: Spray affected areas from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks. Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

Contraindications: There are no known contraindications to this drug when used as directed.

H. Indication

Miconazole nitrate solution is indicated for the treatment of fungal infections in dogs and cats caused by Microsporum canis, Microsporum gypseum and Trichophyton mentagrophytes.

I. Pioneer Product

Conofite (miconazole nitrate) lotion/spray 1%, NADA 95-184

II. EFFECTIVENESS AND BIOEQUIVALENCE

The proposed product, Miconosol (miconazole nitrate) 1% lotion/spray, is a generic copy of the brand name drug product, Conofite (miconazole nitrate) lotion/spray 1%, NADA 95-184. Under this act, the generic copies of animal drug products that have been previously approved can be approved if the generic is bioequivalent to the pioneer. This drug falls under that category and the effectiveness study does not apply. Under the FDA policy implementing the same law, certain drugs are eligible for waivers from in-vivo bioequivalency studies. Med-Pharmex, Inc. applied for and received an approval of a waiver from in-vivo bioequivalency studies based upon the formulation characteristics of the generic product.

III. TARGET ANIMAL SAFETY

Because this drug is a generic copy of a previously approved drug whose safety has been established, no safety studies have been required for this application.

IV. HUMAN FOOD SAFETY

This drug is indicated for use only on dogs and cats. It is not to be used for food-producing animals. Therefore, the issue of residues and human safety does not arise.

V. 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 Miconosol Lotion/Spray 1%, when used under its proposed conditions of use, is safe and effective for the 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.