Freedom of Information Summary.

1. General Information:

   ANADA Number: 200-245

   Sponsor Name and Address:
   Med-Pharmex, Inc.
   2727 Thompson Creek Rd
   Pomona, CA 91767-1861

   Generic Name:
   Nystatin, neomycin sulfate, thiostrepton and triamcinolone acetonide cream.

   Trade Name:
   Derma-Vet Cream.

   Marketing Status: Rx.

2. Indications for Use:

   Derma-Vet Cream is indicated in the management of dermatologic disorders in dogs and cats, 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.

3. Dosage Form(s), Route(s) of Administration and Recommended Dosages and Contraindications:

   Dosage Form:

   Derma-Vet Cream is in the form of a cream which is applied onto the infected area.

   Route(s) of Administration and Recommended Dosages:

   The route of administration is by external application of the cream.
   The recommended dosage is that the cream is to be applied as a thin film. For mild inflammations, application may range from once daily to once a week. For severe conditions, the product may be applied as often as 2 to 3 times daily, if necessary. Frequency of treatment may be decreased as improvement occurs.

Contraindications:

Derma-Vet Cream should not be used opthalmically.

4. TARGET ANIMAL SAFETY AND 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, 1988, 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, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Rather, approval of an ANADA relies on the ANADA sponsor showing that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Derma-Vet Cream. The generic product is administered as a topical ointment and contains the same active and inactive ingredients in the same concentrations as the pioneer product.

5. Human 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.

6. 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 Derma-Vet Cream (neomycin sulfate, nystatin, triamcinolone acetonide, thiostrepton) when used under its proposed conditions of use, is safe and effective for the labeled indications.

Attachment: Generic and pioneer labeling

Generic –

Pioneer –