

Date of Approval: February 4, 2000

FREEDOM OF INFORMATION SUMMARY

1. General Information:

ANADA Number: 200-275.

Sponsor Name and Address:

Med-Pharmex, Inc.

2727 Thompson Creek Rd

Pomona, CA 91767-1861

Generic Name:

Triamcinolone Acetonide Cream

Trade Name:

Medalone Cream

Marketing Status: Rx.

2. Indications for Use:

Medalone Cream (Triamcinolone Acetonide Cream) is indicated for topical treatment of allergic dermatitis and summer eczema in dogs.

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

Dosage Form:

Medalone Cream is a cream which is topically applied to the infected area.

Route(s) of Administration and Recommended Dosages:

The Route of Administration is topical application of the cream.

The Recommended Dosage is that the cream is applied by rubbing into the affected areas two to four times daily for 4 to 10 days. Frequency of treatment may be decreased as improvement occurs.

Contraindications:

Medalone Cream should not be used ophthalmically.

Freedom of Information Summary (Cont'd):**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 Medalone Cream (triamcinolone acetonide cream). The generic product is administered as a topical ointment and contains the same active and inactive ingredients in similar concentrations as the pioneer product.

5. Human Safety:

This drug is indicated for use only on dogs. 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 Medalone Cream (triamcinolone acetonide cream) when used under its proposed conditions of use, is safe and effective for the labeled indications.

Attachment: Generic and pioneer labeling

Generic –

Pioneer –