Date of Approval: July 15, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-565

Thiabendazole, Dexamethasone, Neomycin Sulfate Solution

Dogs and cats

As an aid in the treatment of certain bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats

Sponsored by:

Putney, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-565

B. Sponsor

Putney, Inc.
One Monument Sq.
Suite 400
Portland, ME 04101

Drug Labeler Code: 026637

C. Proprietary Name

Thiabendazole, Dexamethasone, Neomycin Sulfate Solution

D. Product Established Name

thiabendazole, dexamethasone, neomycin sulfate solution

E. Pharmacological Category

Thiabendazole – Antifungal
Dexamethasone – Adrenocortical steroid
Neomycin sulfate – Antimicrobial

F. Dosage Form

Solution

G. Amount of Active Ingredient

40 mg/mL thiabendazole
1 mg/mL dexamethasone
3.2 mg/mL neomycin (from neomycin sulfate)

H. How Supplied

7.5 mL and 15 mL dropper bottles, each in 12 bottle boxes

I. Dispensing Status

Rx

J. Dosage Regimen

Prior to the administration of Dermatologic Solution Thiabendazole, Dexamethasone, Neomycin Sulfate Solution, remove the ceruminous, purulent or foreign materials from the ear canal, as well as the crust which may be associated with dermatoses affecting other parts of the body. The design of the container nozzle safely allows partial insertion into the ear canal for ease of administration. The amount to apply and the frequency of treatment are dependent upon the

severity and extent of the lesions. Five to 15 drops should be instilled in the ear twice daily. In treating dermatoses affecting other than the ear the surface of the lesions should be well moistened (2 to 4 drops per square inch) with the solution twice daily. The volume required will be dependent upon the size of the lesion.

K. Route of Administration

Topical

L. Species/Class

Dogs and cats

M. Indications

Thiabendazole, Dexamethasone, Neomycin Sulfate Solution is indicated as an aid in the treatment of certain bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats.

N. Reference Listed New Animal Drug

TRESADERM; thiabendazole, dexamethasone, neomycin sulfate; NADA 042-633; Merial, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug (RLNAD)). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Putney, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Thiabendazole, Dexamethasone, Neomycin Sulfate Solution. The generic drug product is a topical solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is TRESADERM (thiabendazole, dexamethasone, neomycin sulfate) dermatologic solution, sponsored by Merial, Inc. under NADA 042-633, and was approved as an aid in the treatment of certain bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs and cats, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Thiabendazole, Dexamethasone, Neomycin Sulfate Solution:

For topical use in dogs and cats. Avoid contact with eyes.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain an MSDS, or for assistance call 1-866-683-0660.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Thiabendazole, Dexamethasone, Neomycin Sulfate Solution, when used according to the label, is safe and effective.