Date of Approval: May 17, 2016

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-536

MOMETAVET

Gentamicin sulfate, USP; mometasone furoate anhydrous, USP; and clotrimazole, USP

Otic Suspension

Dogs

For the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci)

Sponsored by:

Med-Pharmex, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-536

B. Sponsor

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

Drug Labeler Code: 054925

C. Proprietary Name

MOMETAVET

D. Product Established Name

gentamicin sulfate, USP; mometasone furoate anhydrous, USP; and clotrimazole, USP

E. Pharmacological Category

Gentamicin – aminoglycoside antibiotic
Mometasone - synthetic adrenocorticoid steroid
Clotrimazole – broad-spectrum antifungal agent

F. Dosage Form

Suspension

G. Amount of Active Ingredient

Each gram contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base; mometasone furoate anhydrous, USP equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP.

H. How Supplied

7.5 g tubes and plastic bottles, 15 g tubes and plastic bottles, 30 g plastic bottles, and 215 g plastic bottles

I. Dispensing Status

Rx

J. Dosage Regimen

The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops from the 7.5 g tubes and bottles, 15 g tubes and bottles, and 30 g bottles (2 drops from the 215 g bottle) once daily in the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the 7.5 g tubes and bottles, 15 g tubes and

bottles, and 30 g bottles (4 drops from the 215 g bottle) once daily in the ear canal. Therapy should continue for 7 consecutive days.

K. Route of Administration

Topical (Otic)

L. Species/Class

Dogs

M. Indications

Mometavet® Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

N. Reference Listed New Animal Drug

MOMETAMAX; gentamicin sulfate, USP; mometasone furoate monohydrate; and clotrimazole, USP; NADA 141-177; Intervet, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C 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, Med-Pharmex, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product MOMETAVET (gentamicin sulfate, USP; mometasone furoate anhydrous, USP; and clotrimazole, USP) otic suspension. The generic drug product is a topical suspension (Otic), contains the same active ingredients 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 MOMETAMAX (gentamicin sulfate, USP; mometasone furoate monohydrate; and clotrimazole, USP) otic suspension, sponsored by Intervet, Inc. under 141-177, and was approved for use in dogs on December 5, 2000.

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, 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 MOMETAVET:

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

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 MOMETAVET, when used according to the label, is safe and effective.