Date of Approval: June 1, 2005

FREEDOM OF INFORMATION SUMMARY

NADA 141-177

MOMETAMAX

gentamicin sulfate, USP; mometasone furoate monohydrate,
and clotrimazole, USP suspension

Supplemental approval to add a new package size (7.5g bottle)

Sponsored by:

Schering-Plough Animal Health Corp.

Table of Contents

1. GENERAL INFORMATION:

a. File Number:	NADA 141-177
b. Sponsor:	Schering-Plough Animal Health Corp. 1095 Morris Ave. Union, NJ 07083 Drug Labeler Code: 000061
c. Established Name:	Gentamicin sulfate, USP; mometasone furoate monohydrate; and clotrimazole, USP suspension
d. Proprietary Name:	MOMETAMAX
e. Dosage Form:	Otic Suspension
f. How Supplied:	7.5g, 15g, 30g, and 215g plastic bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each gram contains 3mg gentamicin, 1mg mometasone, and 10mg clotrimazole
i. Route of Administration:	Topical (otic)
j. Species/Class:	Dogs
k. Recommended Dosage:	For dogs weighing less than 30 lbs, instill 4 drops from the 7.5g, 15g, or 30g bottle into the ear canal (2 drops from the 215g bottle) or, for dogs weighing 30 lbs or more, instill 8 drops from the 7.5g, 15g or 30g bottle into the ear canal (4 drops from the 215g bottle), once daily for 7 days.
l. Pharmacological Category:	Gentamicin - aminoglycoside antibiotic Mometasone - synthetic adrenocorticoid Clotrimazole - imidazole antifungal agent
m. Indications:	MOMETAMAX 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. Effect of Supplement — New package size (7.5g bottle)

2. EFFECTIVENESS:

No new effectiveness data were required to support this supplement application. Effectiveness information for MOMETAMAX Otic Suspension is incorporated by reference to the original A-0000 approval on December 5, 2000 and the supplemental approval C-0010 on January 9, 2003.

3. TARGET ANIMAL SAFETY:

No new safety data were required to support this supplemental application. Target animal safety information for MOMETAMAX Otic Suspension is incorporated by reference to the original A-0000 approval on December 5, 2000.

4. HUMAN SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the package insert as follows: "Keep this and all drugs out of the reach of children."

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that MOMETAMAX when used under the labeled conditions of use is safe and effective for the treatment of otitis externa in dogs.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose otitis externa.

This approval for does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category I change. Therefore, this action did not require a reevaluation of the safety and effectiveness data in the parent application.

Schering-Plough holds the following patents on mometasone:
5,502,222 (expires June 2014)
5,616,742 (expires May 2015)
5,750,745 (expires May 2015)
5,886,200 (expires June 2017)
6,127,353 (expires October 2017)

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Package insert
Bottle label (7.5g)
Carton label (7.5g)
Shipping label (7.5g)