

Date of Approval: November 29, 2010

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-457

MUPIROCIN Ointment, 2%

(mupirocin)

Dogs

Indications: Mupirocin ointment is indicated for the treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

Sponsored by:

Taro Pharmaceuticals U.S.A., Inc.

1. GENERAL INFORMATION:

A. File Number:	ANADA 200-457
B. Sponsor:	Taro Pharmaceuticals U.S.A., Inc. 3 Skyline Drive. Hawthorne, NY 10532. Drug Labeler Code: 51672
C. Proprietary Name(s):	Mupirocin Ointment USP, 2%
D. Established Name(s):	Mupirocin
E. Pharmacological Category:	Antimicrobial
F. Dosage Form(s):	Ointment
G. Amount of Active Ingredient(s):	2% (20 mg/g)
H. How Supplied:	5 g, 15 g, 22 g, and 30 g tubes
I. How Dispensed:	Rx
J. Dosage(s):	Mupirocin ointment should be applied to the affected area twice a day. Apply a sufficient amount of ointment to completely cover the infected area. Maximum duration of treatment should not exceed 30 days.
K. Route(s) of Administration:	Topical
L. Species/Class(es):	Dogs
M. Indication(s):	Mupirocin ointment is indicated for the treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of <i>Staphylococcus aureus</i> and <i>Staphylococcus intermedius</i> .
N. Reference Listed New Animal Drug:	BACTODERM (mupirocin) ointment 2%; NADA 140-839; Pfizer, Inc.

2. 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 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 the product is intended for use in food producing animals and bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2000).

Based on the formulation characteristics of the generic product, Taro Pharmaceuticals U.S.A., Inc., was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product Mupirocin Ointment 2%. The generic product is administered topically, contains the same active ingredient in the same concentration and dosage form as the RLNAD product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The RLNAD is BACTODERM (mupirocin) ointment 2%, the subject of Pfizer Inc., NADA 140-839, approved on September 28, 1988.

3. 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 ANADA.

Human Warnings are provided on the product label as follows: “Keep out of reach of children”, “Federal law restricts this drug to use by or on the order of a licensed veterinarian” and for dermatologic use on dogs”.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Mupirocin Ointment 2%, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved RLNAD labeling are attached as indicated below:

Generic Labeling for ANADA 200-457:

5 g, 15 g, 22 g and 30 g box and tube labels, and box insert

RLNAD Labeling for NADA 140-839:

5 g box, tube and insert