

Approval Date: March 8, 2007

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-418

**MURICIN Ointment 2%
(mupirocin)**

Indicated for the topical treatment of canine bacterial infections of the skin, including superficial pyoderma caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

Sponsored by:

Altana Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-418
- b. Sponsor: Altana Inc.
60 Baylis Road
Melville, NY 11747

Drug Labeler Code: 025463
- c. Established Name: Mupirocin
- d. Proprietary Name: MURICIN Ointment 2%
- e. Dosage Form: Ointment
- f. How Supplied: 15-gram tubes
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each gram contains 20 mg of mupirocin in a bland, water-washable ointment base consisting of polyethylene glycol 400 and polyethylene glycol 3350 (polyethylene glycol ointment, NF).
- i. Route of Administration: Topical
- j. Species/Class: Dogs
- k. Recommended Dosage: Prior to treatment, the lesion should be cleaned. MURICIN Ointment 2% 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.
- l. Pharmacological Category: Antimicrobial
- m. Indications: MURICIN Ointment 2% is indicated for the topical treatment of canine bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

- n. Pioneer Product: BACTODERM Ointment 2%; mupirocin;
NADA 140-839; Pfizer, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

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 (pioneer product). 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 pioneer, 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 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, 2002).

Based on the formulation characteristics of the generic product, Altana Inc. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product MURICIN (mupirocin) Ointment 2%. The generic product is administered as a topical ointment, the same dosage form as the pioneer product. It contains the same active and inactive ingredients in nearly the same concentration as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, BACTODERM (mupirocin) Ointment 2%, the subject of Pfizer, Inc., under NADA 140-839, was 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.

4. 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 MURICIN (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 pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-418:

MURICIN Ointment 2% – Container Label; Box Label; Package Insert

Pioneer Labeling for NADA 140-839:

BACTODERM Ointment 2% – Container Label; Box Label; Package Insert