

Date of Approval: March 26, 2010

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-446

BUTORPHINE Veterinary Injection
(butorphanol tartrate, USP)

Injectable Solution

Indicated for the relief of pain in cats caused by major or minor
trauma, or pain associated with surgical procedures

Sponsored by:
Modern Veterinary Therapeutics, LLC

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-446
- b. Sponsor: Modern Veterinary Therapeutics, LLC
1550 Madruga Ave., Suite329
Coral Gables, FL 33146
- Drug Labeler Code: 015914
- c. Established Names: Butorphanol tartrate, USP
- d. Proprietary Names: BUTORPHINE Veterinary Injection
- e. Dosage Form: Injectable solution
- f. How Supplied: 10 mL vial
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each mL contains 2 mg butorphanol base (as butorphanol tartrate, USP)
- i. Route of Administration: Subcutaneous injection
- j. Species/Class: Cats
- k. Recommended Dosage: 0.4 mg of butorphanol per kilogram body weight (0.2 mg/lb)
- l. Pharmacological Category: Analgesic
- m. Indications: Indicated for the relief of pain in cats caused by major or minor trauma, or pain associated with surgical procedures
- n. Pioneer Product: TORBUGESIC-SA Veterinary Injection; butorphanol tartrate, USP; NADA 141-047; Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc.

2. TARGET ANIMAL SAFETY AND 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 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 Guidance, revised October 9, 2002).

Base on the formulation characteristics of the generic product, Modern Veterinary Therapeutics, LLC was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product BUTORPHINE (butorphanol tartrate, USP) Veterinary Injection. The generic product is administered as an injection, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, TORBUGESIC-SA (butorphanol tartrate, USP) Veterinary Injection, the subject of, Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc. NADA 141-047, was approved on July 5, 1994.

3. HUMAN SAFETY:

This drug is intended for use in cats, 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: **“NOT FOR HUMAN USE”**

4. AGENCY CONCLUSIONS:

This ANADA filed 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 BUTORPHINE Veterinary Injection, 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 200-446:

BUTORPHINE – Bottle label – 10 mL

BUTORPHINE – Package insert – 10 mL

BUTORPHINE – Carton label – 10 mL

Pioneer Labeling for NADA 141-047:

TORBUGESIC-SA – Bottle label – 10 mL

TORBUGESIC-SA – Package insert – 10 mL