Approval Date: May 1, 2008

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-332

BUTORPHIC Injection
(butorphanol tartrate)

Indications for use: For the relief of pain associated with colic and postpartum pain in horses.

Sponsored by:

Lloyd, Inc.

FREEDOM OF INFORMATION SUMMARY

1. General Information:

a. File Number:	ANADA 200-332
b. Sponsor:	Lloyd, Inc. 604 W. Thomas Ave. Shenandoah, Iowa 51601 Drug Labeler Code: 061690
c. Established Name:	Butorphanol tartrate
d. Proprietary Name:	BUTORPHIC Injection
e. Dosage Form:	Solution
f. How Supplied:	20 mL vials
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	10 mg butorphanol base per mL as butorphanol tartrate
i. Route of Administration:	Intravenous injection
j. Species/Class:	Horses
k. Recommended Dosage:	The recommended dosage in the horse is 0.1 mg butorphanol per kilogram of body weight (0.05 mg/lb) by intravenous injection. The dose may be repeated within 3 to 4 hours but treatment should not exceed 48 hours.
l. Pharmacological Category:	Analgesic
m. Indications:	Butorphic Injection is indicated for relief of pain associated with colic in adult horses and yearlings. Clinical studies in the horse have shown that Butorphic Injection alleviates abdominal pain associated with torsion, impaction, intussusception, and tympanic colic, and postpartum pain.

n. Pioneer Product: TORBUGESIC; butorphanol tartrate; NADA 135-780; Fort Dodge Animal Health, Division of Wyeth

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 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, Lloyd, Inc., was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product BUTORPHIC (butorphanol tartrate) Injection. The generic product is administered as an intravenous injectable, contains the same active ingredients 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 (butorphanol tartrate), the subject of Fort Dodge Animal Health, Division of Wyeth, NADA 135-780, was approved on June 11, 1985.

3. HUMAN SAFETY:

This drug is intended for use in horses, 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 the generic product BUTORPHIC Injection, when used under their 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 200-332:
BUTORPHIC Injection – vial and carton labels – 20 mL; package insert

Pioneer Labeling for NADA 135-780:
TORBUGESIC – vial and carton labels – 50 mL; package insert