Date of Approval: January 22, 2003

FREEDOM OF INFORMATION (FOI) SUMMARY

Butorphanol Tartrate Injection

For relief of pain associated with colic in adult horses and yearlings

ANADA 200-322

Phoenix Scientific, Inc.

3915 South 48th Street Terrace

St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

ANADA 200-322

ANADA/GENERIC SPONSOR:
Phoenix Scientific, Inc.
3915 South 48th Street Terrace, St. Joseph, MO 64503

a.	**Established Name:**	Butorphanol Tartrate, USP
b.	**Trade Name/Proprietary Name:**	Butorphanol Tartrate Injection
c.	**Dosage Form:**	Injection
d.	**How Supplied:**	10 mL & 50 mL Type I amber glass bottles
e.	**How Dispensed:**	Rx;Schedule IV(CIV)
f.	**Amount of Active Ingredients**	10 mg butorphanol /mL
g.	**Route of Administration:**	Intravenous Injection
h.	**Species:**	Equine
i.	**Pioneer Product**	Torbugesic® (Butorphanol Tartrate) NADA 135-780

INDICATIONS FOR USE: Butorphanol Tartrate Injection is indicated for the relief of pain associated with colic in adult horses and yearlings.

RECOMMENDED DOSAGE: The recommended dosage in the horse is 0.1 mg of butorphanol per kilogram of body weight, (0.05 mg/lb) by intravenous injection. This is equivalent to 5 mL of Butorphanol Tartrate Injection for each 1000 lbs body weight. The dose may be repeated within 3 to 4 hours but treatment should not exceed 48 hours.

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 shows 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 end-point 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, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product, Butorphanol Tartrate. The generic product is administered as an injectable dosage form, 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, the subject of Fort Dodge Animal Health's NADA 135-780, was approved on June 11, 1985.

3. HUMAN SAFETY:

None required as the product is intended for use in horses only. The labeling contains the statement "Warning: Not to be used in horses intended for food."

Human Safety Relative to Possession, Handling and Administration: Labeling contains adequate caution/warning statements. Butorphanal tartrate is a Schedule IV drug; Rx only.

4. AGENCY CONCLUSIONS:

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

5. ATTACHMENTS: The following **generic** labeling and currently approved **pioneer** labeling are attached.

Generic Labeling **1.** Facsimile package labeling for generic product; 10 mL and 50 mL and package insert.

Pioneer Labeling	**2**	Pioneer package labeling for Torbugesic®; 10 mL and 50 mL and package insert.