Stamp Date: August 26, 2002

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-069

For the treatment of ovarian cysts in dairy cattle.

Sponsored by:

Phoenix Scientific, Inc.
3915 S. 48th Street Terrace
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	200-069
Sponsor:	Phoenix Scientific, Inc. 3915 South 48th Street Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
Generic Name:	gonadorelin diacetate tetrahydrate injection
Trade Name:	Fertelin™(Gonadorelin Diacetate Tetrahydrate) Sterile Solution
Dosage Form:	Injection
How Supplied:	4 mL and 12 mL in glass vials
How Dispensed:	Rx
Amount of Active Ingredients:	50 mcg gonadorelin/mL
Route of Administration:	Intravenous or intramuscular injection
Species:	Dairy cattle
Pioneer Product/ "Listed Product":	Cystorelin® NADA 098-379 (Merial Ltd.)

2. INDICATIONS

Fertelin (Gonadorelin) is indicated for the treatment of ovarian follicular cysts in dairy cattle. Ovarian cysts are non-ovulated follicles with incomplete luteinization which result in nymphomania or irregular estrus.

Historically, cyctic ovaries have responded to an exogenous source of luteinizing hormone (LH) such as human chorionic gonadotropin. Fertelin initiates release of endogenous LH to cause ovulation and luteinization.

3. DOSAGE

The recommended intravenous or intramuscular dosage of Fertelin is 100 mcg/cow.

4. TARGET ANIMAL SAFETY and DRUG EFFECTIVIENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990: Fifth GADPTRA Policy Letter: Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for Gonadorelin Injection. The generic and pioneer products contain the same active ingredients in the same concentration and are injections for intravenous or intramuscular administration.

5. HUMAN FOOD SAFETY:

Tolerance

The tolerances established for the pioneer product apply to the generic product. No tolerances are established for residues of gonadorelin in uncooked edible tissues of cattle.

Withdrawal Time

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product There is a zero-day withdrawal time established for gonadorelin injection.

Regulatory Methods for Residues

None

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.

6. AGENCY CONCLUTIONS:

This is an Abbreviated New Animal Drug Application filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Fertelin Sterile Solution, were established by demonstration of chemical equivalence to the pioneer product, Cystorelin® (NADA 098-379), sponsored by Merial Ltd.

This generic product and the pioneer product have identical labeling indications for use in cattle. The route and method of administration of the two drugs are identical. Both drugs are administered by intravenous or intramuscular injection. The generic and pioneer products contain the same active ingredients. Therefore, in compliance with FDA policy promulgated to implement section 512(b)(2) of FFD&C Act, no additional safety, efficacy, or *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Fertelin Sterile Solution, is safe and effective for its labeled indications when used under the proposed conditions of use.

Attachments:

1. Generic Labeling:

   Package Insert

   Vial Labels, 4 mL and 12 mL

2. Pioneer Labeling

   Package Insert

   Vial Label, 10 mL