Stamp Date:____Feb 12, 1999_____

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-253

ProstaMate™ (dinoprost tromethamine injection) Sterile Solution

For intramuscular use for estrus synchronization, treatment of unobserved (silent) estrus and pyometra (chronic endometritis) in cattle: for abortion of feedlot and other non-lactating cattle; for parturition induction in swine; and for controlling the timing of estrus in estrous cycling mares and clinically anestrous mares that have a corpus luteum.

Sponsored by:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	200-253
Sponsor:	Phoenix Scientific, Inc. 3915 South 48th Street Terrace P.O. Box 6457 St. Joseph, MO 64506-0457
Generic Name:	dinoprost tromethamine, USP
Trade Name:	ProstaMate™ (dinoprost tromethamine injection) Sterile Solution
Dosage Form:	injectable solution
How Supplied:	10 mL and 30 mL multiple dose vials
How Dispensed:	Rx
Amount of Active Ingredients:	Each mL contains 5 mg of dinoprost from dinoprost tromethamine
Route of Administration:	IM Injection
Species:	Cattle, swine, horses
Labeled Dosage	Cattle - 5 mL IM Swine - 2 mL IM Mares - 1 mL IM
Indications for Use:	For intramuscular use for estrus synchronization, treatment of unobserved (silent) estrus and pyometra (chronic endometritis) in cattle: for abortion of feedlot and other non-lactating cattle; for parturition induction in swine; and for controlling the timing of estrus in estrous cycling mares and clinically anestrous mares that have a corpus luteum.

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 (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).

For certain dosage forms, the agency grants a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990: fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study with ProstaMate™ (dinoprost tromethamine injection). The generic and pioneer products are solutions with the same active and inactive ingredients.

3. HUMAN SAFETY

Human Food Safety

Cattle: No Milk discard or preslaughter drug withdrawal period is required for labeled uses.
Swine: No preslaughter drug withdrawal period is required for labeled uses.
Mares: Not for use in horses intended for food.

Human Safety Relative to Possession, Handling and Administration:

The labeling contains adequate Warning statements, as described below.

Not for human use.

Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should, therefore, be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

4. AGENCY CONCLUSION:

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 ProstaMate™ (dinoprost tromethamine injection) Sterile Solution, when used under the proposed conditions of use, is safe and effective for the labeled indications.

Attachments:

1. Generic Labeling:

   Vial Label
   Package Insert
   Carton Label

2. Pioneer Labeling

   Vial Label
   Package Insert
   Carton Label