

Date of Approval: April 29, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-317

DEXIUM-SP

(dexamethasone sodium phosphate injection)

4 mg/mL Injection

Horses

Indications: It is indicated as a rapid adrenal glucocorticoid and/or an anti-inflammatory agent in horses.

Sponsored by:
Cross Vetpharm Group Ltd.
Tallaght, Dublin 24, Ireland

FREEDOM OF INFORMATION SUMMARY

1. **GENERAL INFORMATION:**

- a. File Number: ANADA 200-317
- b. Sponsor: Cross Vetpharm Group Ltd.
Broomhill Road
Tallaght, Dublin 24, Ireland

Drug Labeler Code: 061623
- c. Established Name: Dexamethasone sodium phosphate injection
4 mg/mL
- d. Proprietary Name: DEXIUM-SP
- e. Dosage Form: Injectable solution
- f. How Supplied: 100 mL multiple dose vial
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each mL contains 4 mg dexamethasone
sodium phosphate
- i. Route of Administration: Intravenously
- j. Species/Class: Horses
- k. Recommended Dosage: 2.5 to 5 mg intravenously
(based on 3 mg/ mL dexamethasone content)
- l. Pharmacological Category: Anti-inflammatory
- m. Indications: For use as a rapid adrenal glucocorticoid
and/or anti-inflammatory agent in horses.

- n. Pioneer Product: Dexamethasone Sodium Phosphate Injection, USP (dexamethasone sodium phosphate injection); Steris Laboratories, Inc., NADA 104-606

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 (GADPTR) 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 drug 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 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 conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTR Policy Letter; Bioequivalence Guideline, October 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement for *in vivo* bioequivalence study for the generic product DEXIUM-SP (dexamethasone sodium phosphate injection). The generic product is administered as an injectable solution, 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 ingredients. The pioneer product, Dexamethasone Sodium Phosphate Injection, USP (dexamethasone sodium phosphate injection), the subject of Steris Laboratories, Inc., NADA 104-606, was approved on May 13, 1977.

3. HUMAN SAFETY:

This drug is indicated for use only 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.

Human warnings are provided on the product label as follows: **“For Animal Use Only”**
“Keep Out of Reach of Children.”
“Not For Use in Horses Intended For food”

4. AGENCY CONCLUSIONS:

This ANADA submitted 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 DEXIUM-SP, 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 indicated below:

Pioneer Labeling for NADA 104-606:

Dexamethasone Sodium Phosphate Injection, USP-100 mL vial size and insert

Generic Labeling for ANADA 200-317

DEXIUM-SP-100 mL vial size and insert