Date of Approval: October 20, 2003

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-312

DEXIUM

(dexamethasone)

2 mg/mL Injection

Cattle, Horses, Dogs, and Cats

Indications for use: For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle, horses, dogs, and cats.

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

FREEDOM OF INFORMATION SUMMARY

1. *GENERAL INFORMATION*:

a. File Number:	ANADA 200-312
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623
c. Established Name:	Dexamethasone
d. Proprietary Name:	DEXIUM
e. Dosage Form:	Injectable solution
f. How Supplied:	100 mL multiple dose vial
g. How Dispensed:	Rx
h. Amount of Active Ingredient:	Each mL contains 2 mg of dexamethasone.
i. Route of Administration:	Intravenously or intramuscularly
j. Species/Class:	Bovine, equine, canine & feline
k. Recommended Dosage:	Bovine - 5 to 20 mg intravenously or intramuscularly. Equine - 2.5 to 5 mg intravenously or intramuscularly. Canine - 0.25 to 1 mg intramuscularly or intravenously. The dose may be repeated for three (3) to five (5) days. Feline - 0.125 to 0.5 mg intravenously or intramuscularly. The dose may be repeated for three (3) to five (5) days.

l. Pharmacological Category:	Anti-inflammatory.
m. Indications:	For treatment of primary bovine ketosis and as an anti-inflammatory agent in the canine, feline, bovine and equine.
n. Pioneer Product:	AZIUM (dexamethasone); NADA 12-559 Schering-Plough Animal Health

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 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 GADPTRA 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 (dexamethasone). 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, AZIUM (dexamethasone), the subject of Schering-Plough Animal Health, NADA 12-559, was approved on March 29, 1961.

3. HUMAN SAFETY:

· **Tolerance**

A tolerance is not required because one was not required for the pioneer product.

· **Withdrawal Time**

A withdrawal period is not required because one was not required for the pioneer product.

· **Regulatory Method for Residues**

A regulatory method is not required because one was not required for the pioneer product.

Human warnings are provided on the product label as follows: **"For Animal Use Only"** **"Keep Out of Reach of Children"**

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, 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 12-559:
AZIUM-100 mL vial size and insert

Generic Labeling for ANADA 200-312
DEXIUM-100 mL vial size and insert