Date of Approval: August 19, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-324

Dexamethasone Injection, 2 mg/mL
(2 mg dexamethasone)

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

Sponsored by:
Veterinary Laboratories, Inc.
Lenexa, KS 66215

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-324
b. Sponsor:	Veterinary Laboratories, Inc. 12340 Santa Fe Drive Lenexa, KS 66215 Drug Labeler Code: 000857
c. Established Name:	Dexamethasone Injection
d. Proprietary Name:	Dexamethasone Injection 2 mg/mL
e. Dosage Form:	Injectable
f. How Supplied:	100 mL multiple dose vial
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each mL contains: 2 mg dexamethasone; 500 mg polyethylene glycol 400; 9 mg benzyl alcohol, 1.8 mg methylparaben, and 0.2 mg propylparaben as preservatives; 4.75% alcohol; HCl to adjust pH to approximately 4.9; water for injection qs.
i. Route of Administration:	Intravenously or intramuscularly
j. Species/Class:	Bovine and equine
k. Recommended Dosage:	Bovine-5 to 20 mg Equine-2.5 to 5 mg

l. Pharmacological Category:	Anti-inflammatory.
m. Indications:	Treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses.
n. Pioneer Product:	Azium® manufactured by Schering-Plough Animal Health (NADA 12-559)

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 2000).

Based upon the formulation characteristics of the generic product, Veterinary Laboratories, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for Dexamethasone Injection 2 mg/mL. The generic and the pioneer product (injectable solutions) contain the same active and inactive ingredients in the same concentration. The pioneer product, Azium®, the subject of Schering-Plough Animal Health's NADA 12-559, was approved on March 29, 1961.

3. HUMAN SAFETY:

There is no tolerance or withdrawal period associated with this or the pioneer product. Therefore, no human safety data pertaining to residues in food were required.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (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 Dexamethasone Injection, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Labeling:

Pioneer Labeling for NADA 12-559:
Azium®-100 mL vial size and insert

Generic Labeling for ANADA 200-324

Dexamethasone Injection- 100 mL vial size and insert