Approval Date: February 10, 2003

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 139-236

Cervizine 300
(xylazine hydrochloride)

Lloyd, Inc.
P.O. Box 130
604 West Thomas Avenue
Shenandoah, IA 51601-0130

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

a. File Number: Supplemental New Animal Drug Application (S/NADA) 139-236

b. Sponsor: LLOYD, Inc.
604 W. Thomas Avenue
P.O. Box 130
Shenandoah, Iowa 51601-0130

Drug Labeler Code: 061690

c. Established Name: Xylazine hydrochloride

d. Proprietary Name: Cervizine 300 Injectable

e. Dosage Form: Injectable 300 mg/mL sterile solution

f. How Supplied: 20 mL multiple dose vials

g. How Dispensed: Prescription (Rx)

h. Amount of Active Ingredients: Xylazine hydrochloride 300 mg/mL solution

i. Route of Administration: Intramuscular

j. Species/Class: Fallow Deer, Mule Deer, Sika Deer, White-tailed Deer, and Elk/Cervidae

k. Recommended Dosage:

Fallow Deer (*Dama dama*) – 0.67 to 1.33 mL/100 lbs body weight (2.0 to 4.0 mg/lb or 4.4 to 8.8 mg/kg);

Mule (*Odocoileus hemionus*), Sika (*Cervus nippon*) & White-tailed (*Odocoileus virginianus*) Deer – 0.33 to 0.67 mL/100 lbs body weight (1.0 to 2.0 mg/lb or 2.2 to 4.4 mg/kg);

Elk (*Cervus canadensis*) – 0.08 to 0.17 mL/100 lbs Bodyweight (0.25 to 0.5 mg/lb or 0.55-1.1 mg/kg)

l. Pharmacological Category: Sedative/Analgesic

m. Indications: Xylazine should be used in Cervidae (Fallow Deer, Mule Deer, Sika Deer, White-tailed Deer and Elk) when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia. Xylazine may be used for the following:

1. To calm and facilitate handling of fractious animals.
2. Diagnostic procedures.
3. Minor surgical procedures.
4. Therapeutic medication for sedation and relief of pain following injury or surgery.
5. As a preanesthetic to local anesthetic. Cervizine 300 at the recommended dosages can be used in conjunction with local anesthetics, such as procaine or lidocaine.

n. Effect of Supplement: This supplement provides for a 300 mg/mL xylazine concentration, in addition to the approved concentration of 100 mg/mL for Cervidae.

2. EFFECTIVENESS:

AnaSed (xylazine hydrochloride) 100 mg/mL and Cervizine 300 Injectable (xylazine hydrochloride) 300 mg/mL are injectable solutions that contain the same active and inactive ingredients and are buffered to the same pH. Xylazine hydrochloride is freely soluble in water at 100 mg/mL and 300 mg/mL. Based on the formulation characteristics of the proposed xylazine product, no additional effectiveness studies were required for approval of the xylazine 300 mg/mL product.

3. TARGET ANIMAL SAFETY:

AnaSed (xylazine hydrochloride) 100 mg/mL and Cervizine 300 Injectable (xylazine hydrochloride) 300 mg/mL are injectable solutions that contain the same active and inactive ingredients and are buffered to the same pH. Xylazine hydrochloride is freely soluble in water at 100 mg/mL and 300 mg/mL. Based on the formulation characteristics of the proposed xylazine product, no additional studies were required for approval of the xylazine 300 mg/mL product.

4. HUMAN SAFETY:

This drug is intended for use in Fallow, Mule, Sika, and White-Tailed deer and Elk, 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 animals were not required for approval of this supplemental NADA.

Human Warnings are provided on the product label as follows: "Avoid accidental administration to humans. Should such exposure occur, notify a physician immediately. Artificial respiration may be indicated. Do not use in Cervidae less than 15 days before or during the hunting season."

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (FFDCA), and Section 514 of the implementing regulations. The data demonstrate that Cervizine 300, when administered under labeled conditions of use, is safe and effective for use in Cervidae (Fallow Deer, Mule Deer, Sika Deer, White-tailed Deer and Elk) when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is judged to be critical for the assessment of conditions requiring its use as well as for proper use of the drug.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change; therefore, this action did not require a reevaluation of the safety and effectiveness data in the parent application.

Cervizine 300 Injectable is under the following U.S. Patent Numbers:

U.S. Patent Number	Date of Expiration
4,614,798	September 30, 2003

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

a. Vial Label
b. Individual Box Label
c. Package Insert