

I. GENERAL INFORMATION

A. File Number

NADA 139-236

B. Sponsor

Lloyd, Inc.
(formerly Vet-A-Mix, Inc.)
604 W. Thomas Avenue
P.O. Box 86 Shenandoah, Iowa 51601

C. Proprietary Name

AnaSed; Injectable

D. Established Name

xylazine 100 mg/mL

E. Dosage Form

Sterile Solution

F. Dosage Regimen

Deer:

Fallow Deer (*Dama dama*): 2.0 to 4.0 mL/100 lbs. body weight (2.0 to 4.0 mg/lb)
Mule (*Odocoileus hemionus*), Sika (*Cervus nippon*) & White-tailed (*Odocoileus virginianus*) Deer: 1.0 to 2.0 mL/100 lbs. body weight (1.0 to 2.0 mg/lb)

Elk:

Elk (*Cervus canadensis*): 0.25 to 0.5 mL/100 lbs. body weight (0.25 to 0.5 mg/lb)

G. Route of Administration

Intramuscularly

H. Indication

AnaSed may be used in 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. it 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. AnaSed at the recommended dosages can be used in conjunction with local anesthetics, such as procaine or lidocaine.

I. Effect of Supplement

This supplement provides for modification of the labeling to include use of AnaSed; 100 mg/mL in Fallow Deer, Mule Deer, Sika Deer, White-tailed Deer, and Elk.

II. TARGET ANIMAL SAFETY AND 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 may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data and drug effectiveness data, were not required for approval of this generic application as a supplement to existing NADA 139-236. This application relies on the target animal safety and drug effectiveness data in the pioneer's new animal drug application as regards to deer and elk. Ordinarily, the sponsor shows that the generic product is bioequivalent to the pioneer. Bioequivalence is usually demonstrated through a blood level study.

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, April 1990). Based upon the formulation characteristics of the generic product, Vet-A-Mix, Inc. (now known as Lloyd, Inc.) was granted a waiver from conducting an in vivo bioequivalence study for xylazine hydrochloride solution. The generic and pioneer products are solutions with the same active and inactive ingredients. The generic and pioneer products also contain the same concentration of active ingredient. The waiver was granted on December 11, 1991 (photocopy attached).

III. HUMAN FOOD SAFETY

Data on human food safety, pertaining to consumption of drug residues in food, were not required for approval of this supplement. This drug is labeled for use in horses, deer and elk and should not be administered to food-producing animals.

IV. AGENCY CONCLUSIONS

This is a supplement to a New Animal Drug Application filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this supplemental claim for the new animal drug, AnaSed® Injectable (xylazine hydrochloride, 100 mg/mL), were established by demonstration of chemical equivalence to the pioneer product, Rompun® (xylazine hydrochloride, 100 mg/mL, NADA 47-956).

The supplement provides for identical labeling for both products. The route and method of administration of the two drugs are identical. Both drugs are administered intramuscularly. Although the formulation of the AnaSed® differs from that of Rompun® in that the buffering system used in the AnaSed® employs slightly different ingredients at slightly different concentrations, both products are buffered to approximately the same final pH. The formulation differences are not anticipated to affect the bioavailability of the active ingredient, xylazine. Therefore, in compliance with FDA policy promulgated to implement Section 512(b)(2) of the FFD&C Act, no

additional safety, efficacy, or in vivo bioequivalency studies were necessary or required.

This supplement to an NADA satisfies the requirements of section 512 of the Act and demonstrates that AnaSed® is safe and effective for its labeled indications when used under its proposed conditions of use.

V. ATTACHMENTS

- 1) Copy of waiver letter.
- 2) Generic (FINAL) and Pioneer Labeling (MOST CURRENT).
- 3) Generic Labeling
 - a. Vial Label
 - b. Package Insert (page 1) Horse and Cervidae
 - c. Package Insert (page 2) Horse and Cervidae
 - d. Individual Carton
 - e. 6X Overpack Carton View 1
 - f. 6x Overpack Carton View 2
- 4) Pioneer Labeling
 - a. Vial Label
 - b. Package Insert (page 1) Horse
 - c. Package insert (page 2) Horse
 - d. Article Reprint #31 (pages 1-8) Cervidae
 - e. Individual Carton
 - f. 6X Overpack Carton View 1
 - g. 6X Overpack Carton View 2

Copies of these attachments may be obtained by writing to the:
Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.