Approval Date: May 16, 1995

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, 20 mg/mL

D. Established Name

xylazine hydrochloride

E. Dosage Form

Sterile Solution

F. Dispensing Status

Rx

G. Dosage Regimen

Intravenous - 0.5 mL/20 lb. body weight (0.5 mg/lb. or 1.1 mg/kg);
Intramuscular or Subcutaneous - 1.0 mL/20 lb. body weight (1.0 mg/lb., or 2.2 mg/kg)

H. Route of Administration

Intravenously, Intramuscularly, or Subcutaneously

I. Indication

Xylazine should be used in dogs and cats when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia. Xylazine has been used successfully as follows:

1) Diagnostic procedures - examination of mouth and ears, abdominal palpation, rectal palpation, vaginal examination, catheterization of the bladder and radiographic examination of head and extremities.
2) Orthopedic procedures, such as application of casting materials and splints.
1) Dental procedures.
2) Minor surgical procedures of short duration such as debridement, removal of cutaneous neoplasms and suturing of lacerations.
3) To calm and facilitate restraint of fractious animals.
4) Major surgical procedures:
    a. When used as a preanesthetic to general anesthesia

b. When used in conjunction with local anesthetics.

Pioneer Product:
Rompun® (xylazine) 20 mg/mL Injectable, NADA 47-955 by Bayer Corporation, Agriculture Division, Animal Health.

J. Effect of Supplement

This supplement provides for modification of the labeling to include use of AnaSed® 20 mg/mL in cats.

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 (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). For certain dosage forms, the Agency grants a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Vet-A-Mix Animal Health was granted a waiver December 17, 1991, (photocopy attached) from conducting an in vivo bioequivalence study with AnaSed® 20 mg/mL for the additional indication for use in cats. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient.

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 dogs and cats 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, 20 mg/mL), were established by demonstration of chemical equivalence to the pioneer product, Rompun® (xylazine hydrochloride, 20 mg/mL, NADA 47-955).

The two products have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered intramuscularly, subcutaneously, or intravenously. 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) AnaSed® product label
2) AnaSed® package label
3) AnaSed® package insert
4) AnaSed® carton label
5) Rompun® package insert
6) Rompun® product label
7) Rompun® carton label

Copies of these labels 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.