Approval Date: July 12, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-184

B. Sponsor

Chanelle Pharmaceutical Manufacturing Ltd.
Loughrea, County Galway
Ireland

C. Proprietary Name

Chanazine® 20 mg/mL

D. Established Name

Xylazine hydrochloride, 20 mg/mL

E. Dosage Form

Solution

F. Amount of Active Ingredient

Each mL contains 20 mg xylazine, base equivalent

G. How Supplied

20 mL multiple dose vials

H. Dispensing Status

Rx

I. Dosage Regimen

Intravenously-0.5 mL/20 lbs body weight (0.5 mg/lb)

Intramuscularly or subcutaneously-1 mL/20 lbs body weight (1 mg/lb)

In large dogs (over 50 lbs), a dosage of 0.5 mg/lb administered intramuscularly may provide sufficient sedation and/or analgesia for most procedures.

These doses produce sedation which is usually maintained for 1 to 2 hours and analgesia which lasts for 15 to 30 minutes.

J. Route of Administration

Intravenous, intramuscular, or subcutaneous

K. Species/Class

Dogs and cats

L. Indication

Chanazine (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:

Diagnostic procedures - examination of mouth and ears, abdominal palpation, rectal palpation, vaginal examination, catheterization of the bladder and radiographic examinations.

Orthopedic procedures, such as application of casting materials and splints.

Dental procedures.

Minor surgical procedures of short duration such as debridement, removal of cutaneous neoplasms and suturing of lacerations.

To calm and facilitate restraint of fractious animals.

Therapeutic medication for sedation and relief of pain following injury or surgery.

Major surgical procedures:

When used as a preanesthetic to general anesthesia.
When used in conjunction with local anesthetics.

M. Pioneer Product

Rompun® (xylazine) 20 mg/mL Injectable, NADA 047-955 by Bayer Corporation., Agriculture Division, Animal Health

II. 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, (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, Chanelle Manufacturing Pharmaceutical, Ltd. was granted a waiver June 15, 1992 (photocopy attached) from conducting an *in vivo* bioequivalence study with Chanazine® 20 mg/mL Injectable. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient. It is intended for intravenous, intramuscular, and subcutaneous injection.

III. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption
Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. This drug is labeled for use in dogs and cats only and should not be administered to food-producing animals.

Human Safety Relative to Possession, Handling, and Administration
Labeling contains adequate caution/warning statements.

IV. AGENCY CONCLUSIONS

This is an abbreviated new animal drug application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Chanazine® 20 mg/mL Injectable, were established by demonstration of chemical equivalence to the pioneer product, Bayer Corporation's Rompun® 20 mg/mL Injectable (xylazine hydrochloride, 20 mg/mL, NADA 047-955).

This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered by intravenous, intramuscular, or subcutaneous injection. The generic and pioneer products are both solutions that contain the same active and inactive ingredients in the same concentrations. Both products have the same pH. Therefore, consistent with FDA policy implementing Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or *in vivo* bioequivalency studies were necessary or required. This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Chanazine is safe and effective for its labeled indications when used under its proposed conditions of use.

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.