

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-139

B. Sponsor

Chanelle Pharmaceutical Manufacturing Ltd.
Loughrea, County Galway
Ireland

C. Proprietary Name

Chanazine® 100 mg/mL Injectable

D. Established Name

xylazine hydrochloride

E. Dispensing Status

Rx

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

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 November 26, 1991 (photocopy attached) from conducting an *in vivo* bioequivalence study with Chanazine® 100 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 solely for intravenous and intramuscular 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 horses and *Cervidae* 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® 100 mg/mL Injectable, were established by demonstration of chemical equivalence to the pioneer product, Bayers' Rompun® 100 mg/mL Injectable (xylazine hydrochloride, 100 mg/mL, NADA 047-956).

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 or intramuscular 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.