Approval Date: August 3, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-055

B. Sponsor

Lloyd Incorporated
604 W. Thomas Avenue
P.O. Box A
Shenandoah, Iowa 51601

C. Proprietary Name

VetaKet™

D. Established Name

ketamine hydrochloride solution, USP

E. Dosage Form

Injectable solution

F. Amount of Active Ingredient

100 mg ketamine hydrochloride per mL

G. How Supplied

10 mL vials

H. Dispensing Status

Rx

I. Dosage Regimen

Cats: A dose of 11 mg/kg (5 mg/lb) is recommended to produce restraint. Dosages from 22 to 33 mg/kg (10 to 15 mg/lb) produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation.

Subhuman Primates: The dose varies from 3 to 15 mg/kg, depending on the species.

J. Route of Administration

Injection

K. Species/Class

Cats and subhuman primates

L. Indication

VetaKet™ may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

Pioneer Product/Listed Product: Vetalar® (NADA 045-290, Fort Dodge Laboratories)

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). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on bioeqivalence with the pioneer product to demonstrate target animal safety, drug effectiveness, and human safety.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter: 55 FR 24645, June 18, 1990; Bioequivalence Guidance: 61 FR 26182 - 26186, May 24, 1996).

Based upon the formulation characteristics of the generic product, Lloyd Incorporated was granted a waiver from conducting an in vivo bioequivalence study for VetaKet™. The generic and pioneer products contain the same active and inactive ingredients and are injectable solutions.

III. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption:

None required as VetaKet™ Liquid is intended for use only in cats and subhuman primates. The labeling includes the statement, "For Intramuscular use in Cats and Subhuman Primates Only".

Human Safety Relative to Possession, Handling, and Administration:

Labeling contains adequate caution/warning statements.

IV. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Vetaket™ (ketamine hydrochloride injection, USP), when used under the proposed conditions of use, is safe and effective for the labeled indications.

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.