Approval Date: June 26, 1995

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-144

B. Sponsor

Rhone Merieux, Canada, Inc.
345 Boul. Labbe Blvd, N.
Victoriaville, QC, G6P lB 1
Canada

C. Proprietary Name

Undetermined

D. Established Name

Oxytetracycline Hydrochloride

E. Pharmacological Category

Antibiotic

F. Dosage Form

Soluble Powder

G. Amount of Active Ingredient

166 grams Oxytetracycline HCL per pound of powder

H. How Supplied

OXYTETRACYCLINE HCL SOLUBLE POWDER 9.87 oz packet or 3.09 lb bottle

I. Dispensing Status

OTC

J. Dosage Regimen

Administer in water proportioners at a dosage of 1 oz of stock solution to 1 gallon (3.8 liters) of drinking water and administer for 7 to 14 days to poultry, and 5 days to swine.

K. Species/Class

Chickens, Turkeys and Swine

L. Indication

- OXYTETRACYCLINE HCL SOLUBLE POWDER is for control of *Mycoplasma synoviae*, *M. gallisepticum*, *Escherichia coli*, and *Pasteurella multocida* in Chickens.

- for control of *Hexamita meleagridis*, *Mycoplasma synoviae*, transmissible eneritis and coronaviral enteritis in Turkeys.

- for control and treatment of *Escherichia coli*, *Salmonella choleraesuis*, *Pasteurella multiocida* and *Leptospira pomona* in Swine.

M. Reference Listed New Animal Drug

I.D. Russell's Oxytet Soluble ®, NADA 130-435

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 the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. 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 (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Rhone Merieux formally, Sanoff Sante Animale, Canada, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for OXYTETRACYCLINE HYDROCHLORIDE. The generic and pioneer products contain the same active ingredient and are administered as drinking water solutions.

III. HUMAN FOOD SAFETY

Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 3 ppm is established for uncooked kidney and a tolerance of 1 ppm is established for uncooked muscle, liver, fat and skin in chickens and turkeys (21 CFR 556.500(a)). A tolerance of 0.1 ppm is established for the uncooked edible tissues of swine (21 CFR 556.500(b)).

Withdrawal Time

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal times for oxytetracycline HC1 soluble powder are established under 21 CFR 520.1660d: 13 days for swine; 5 days for turkeys; zero days for chickens; oxytetracycline HC1

soluble powder is not for use in chickens or turkeys producing eggs for human consumption.

Regulatory-Method for Residues
The analytical method for the detection of residues of oxytetracycline is a microbiological test using *Bacillus cereus* var. mycoides. This method may be found in Antibiotic Residues in Milk, Dairy-Products, and Animal Tissues: Methods, Reports, and Protocols, revised October 1968, reprinted December 1974. National Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

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 oxytetracycline hydrochloride when used under the proposed conditions of use, is safe and effective for its 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.