DATE OF APPROVAL LETTER: APRIL 21, 2003

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-144

TETROXY® HCA (oxytetracycline HCl)

"additional pouch size for use in swine only"

Sponsored by
Cross Vetpharm Group Limited
Tallaght, Dublin 24, Ireland

1. GENERAL INFORMATION:

a.	*File Number:*	ANADA 200-144
b.	*Sponsor:*	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623
c.	*Established Name:*	Oxytetracycline HCl
d.	*Proprietary Name:*	TETROXY® HCA-1772
e.	*Dosage Form:*	Soluble Powder
f.	*How Supplied:*	1772 g (3.91 lbs) pouch size (new)
g.	*How Dispensed:*	OTC
h.	*Amount of Active Ingredients:*	648 g of oxytetracycline per pouch
i.	*Route of Administration:*	Oral, *via* water
j.	*Species/Class:*	Swine
k.	*Recommended Dosage:*	10 mg/lb body weight daily
l.	*Pharmacological Category:*	Antibiotic
m.	*Indications:*	Swine: FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE – Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona,* susceptible to oxytetracycline.

n. Pioneer Product: TETRAVET-CA, Alpharma, Inc., NADA 130-435

o. Effect of the Supplement: Addition of a new pouch size (3.91 lbs; 1772g) for use in swine

2. 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 (GADPTRA) of 1988, 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 and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily the ANADA Sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, TETROXY® HCA-1772 was granted a waiver from conducting an *in vivo* bioequivalence study and approved on June 26, 1995. The generic and pioneer products contain the same active and inactive ingredients and are soluble powders.

3. HUMAN SAFETY:

A. Tolerances for Residues:

Tolerances are established in 21 CFR 556.500 for the sum of residues in tissues of swine as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney. The acceptable daily intake (ADI) for total oxytetracycline residues is 25 micrograms per kilogram of body weight per day.

B. Withdrawal Times:

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 time for pioneer oxytetracycline soluble powder (NADA 130-435, Alpharma, Inc.'s Oxytet Soluble®) is established under 21 CFR 520.1660d.

C. **Regulatory Method for Residues**:

The regulatory method for determination of oxytetracycline in tissues is a microbiological assay procedure using *Bacillus cereus* var. *mycoides* (ATCC 11778) suspension and is found in the FDA publication "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols" revised October 1968, reprinted December 1974.

4. AGENCY CONCLUSIONS:

This supplemental ANADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) which demonstrates that TETROXY® HCA-1772 (oxytetracycline HCl), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

APPROVED PRODUCT LABELING

A. Pioneer Facsimile label – TETRAVET-CA 1772 g (3.91 lbs)

B. Generic Facsimile label – TETROXY® HCA-1772 1772 g (3.91 lbs)

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 20855

Or requests may be sent via fax to: (301) 443-1746. If there are problems sending a fax, call (301) 827-6567.