

HTA-305

DATE OF APPROVAL LETTER: APR 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

FOIS

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.

HEPRAVEI-CA

(OXYTETRACYCLINE HCl) • AN ANTIBIOTIC

FOR USE IN DRINKING WATER ONLY • NOT FOR USE IN LIQUID FEED SUPPLEMENTS

This packet contains 648 grams of oxytetracycline HCl

This packet will treat 64,800 pounds of swine

NET WT. 3.91 LBS. (1772 GRAMS) • KEEP OUT OF REACH OF CHILDREN

NADA #130-435, APPROVED BY FDA

MIXING DIRECTIONS FOR WATER MEDICATION

Disease	Treatment Level
<p>FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE - Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i>, susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i>, susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i>, susceptible to oxytetracycline.</p>	<p>10 mg/lb. body weight</p>

DIRECTIONS FOR USE

Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. Administer up to 5 days to swine. Note: The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption.

- CAUTION -

Use as sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine.

WARNING - Discontinue treatment of swine 13 days prior to slaughter.

LIVESTOCK REMEDY. NOT FOR HUMAN CONSUMPTION. HAZARDOUS REMEDY.

TAKE TIME



RECOMMENDED PACKET
 STORAGE CONDITIONS:
 Store below 77° F (25° C).

Consult Material Safety
 Data Sheet Prior to Use.

LIST #2203

OBSERVE LABEL DIRECTIONS

MFG'D BY I.D. RUSSELL CO. LABORATORIES • LONGMONT, COLORADO 80501

AUG - 6 2002

000002

14"

Tetroxy HCA-1772

Soluble Powder

(OXYTETRACYCLINE) HCl
ANTIBIOTIC

Net Weight 3.6 lbs (1.63 kg) (1772 grams)
Net Weight 1.8 lbs (0.81 kg) (886 grams)
Net Weight 0.9 lbs (0.41 kg) (443 grams)
Net Weight 0.45 lbs (0.20 kg) (221.5 grams)
Net Weight 0.225 lbs (0.10 kg) (110.75 grams)



NET WEIGHT 3.6 lbs (1.63 kg) (1772 grams)

ELI LILLY AND COMPANY
INDIANAPOLIS, IN 46206

2" gap

19"

AUG - 6 2002
000005

grey area
represents
non-print area
for 3/4" seal

yellow area
represents
pattern variation

10" x 6.5"
print area
frontback

Pantone colors:
pantone 032
princess yellow
black

MIXING INSTRUCTIONS FOR WATER MEDICATION

Disease	Treatment Level
<p>S W I N E</p> <p>FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE: Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i>, susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i>, susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i>, susceptible to oxytetracycline.</p>	<p>10mg/lb body weight</p>

DIRECTIONS FOR USE: MIX FRESH SOLUTIONS DAILY. USE AS SOLE SOURCE OF DRINKING WATER. DO NOT MIX THIS PRODUCT DIRECTLY WITH MILK OR MILK REPLACERS. ADMINISTER ONE HOUR BEFORE OR TWO HOURS AFTER FEEDING MILK OR MILK REPLACERS. ADMINISTER UP TO 5 DAYS TO SWINE.

NOTE: The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animals, feed consumption rate, and the environmental temperature and humidity, each of which affects water consumption.

CAUTION: USE AS SOLE SOURCE OF OXYTETRACYCLINE.
NOT TO BE USED FOR MORE THAN 5 CONSECUTIVE DAYS IN SWINE.

WARNING: DISCONTINUE TREATMENT OF SWINE 0 DAYS PRIOR TO SLAUGHTER.  CONSULT MATERIAL SAFETY DATA SHEET PRIOR TO USE. 

TAKE TIME



USE THE LABEL
DIRECTIONS

Telcort is a registered trademark of the Cross International Group, Ltd. DEA Biotech, Inc.
RECOMMENDED PACKET STORAGE CONDITIONS: Store below 77°F (25°C).
FOR ANIMAL USE ONLY. NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.

Product No. TTE015
81E1037-02



AUG - 6 2002

000004