Approval Date: June 27, 2007

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-452

OXYTET 10 Injection
(oxytetracycline hydrochloride)

Indicated in beef cattle, beef calves, non-lactating dairy cattle and dairy calves for the treatment of the following disease conditions caused by one or more of the oxytetracycline sensitive pathogens listed as follows: bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; bacterial enteritis (scours) caused by *Escherichia coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum;* wooden tongue caused by *Actinobacillus lignieresii;* and wound infections, acute metritis and traumatic injury caused by susceptible strains of streptococcus and staphylococcus organisms.

Sponsored by
Norbrook Laboratories, Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a.	File Number:	ANADA 200-452
b.	Sponsor:	Norbrook Laboratories, Ltd. Station Works, Newry BT35 6JP, Northern Ireland Drug Labeler Code: 055529
c.	Established Name:	Oxytetracycline hydrochloride
d.	Proprietary Name:	OXYTET 10 Injection
e.	Dosage Form:	Injectable
f.	How Supplied:	100 mL, 250 mL, & 500 mL
g.	How Dispensed:	OTC
h.	Amount of Active Ingredients:	Each mL contains 100 mg of oxytetracycline hydrochloride
j.	Species/Class:	Beef cattle, beef calves, non-lactating dairy cattle, and dairy calves
k.	Recommended Dosage:	p3-5 mg/mL body weight per day for a maximum of 4 consecutive days. For intravenous administration only.
l.	Pharmacological Category:	Antimicrobial
m.	Indications:	The use of OXYTET 10 Injection is indicated in beef cattle, beef calves, non-lactating dairy cattle and dairy calves for the treatment of the following disease conditions caused by one or more of the oxytetracycline sensitive pathogens listed as follows Bacterial Pneumonia and Shipping Fever Complex associated with *Pasteurella* spp.; Bacterial Enteritis (scours) caused by *Escherichia coli*; Necrotic Pododermatitis (Foot Rot) and Calf Diphtheria caused by *Fusobacterium necrophorum;* Wooden Tongue caused by *Actinobacillus lignieresii;* and Wound Infections, Acute Metritis and Traumatic Injury caused by susceptible strains of streptococcus and staphylococcus organisms.

n. Pioneer Product: MEDAMYCIN-100; oxytetracycline hydrochloride; NADA 108-963; Boehringer Ingelheim Vetmedica, Inc.

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

Ordinarily, the ANADA sponsor is required to show that 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 9, 2002).

Based on the formulation characteristics of the generic product, Norbrook Laboratories, Ltd. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product OXYTET 10 Injection. The generic product contains the same active and inactive ingredients in the same concentrations and dosage form as the pioneer product and is a sterile solution intended for intravenous use in cattle. The pioneer product, MEDAMYCIN-100 (oxytetracycline hydrochloride) Injectable, the subject of Boehringer Ingelheim Vetmedica, Inc., under NADA 108-963, was approved on December 12, 1978.

3. HUMAN FOOD SAFETY:

- **Tolerance for Residues**
  The tolerances established for the pioneer product apply to the generic product. Tolerances are established for the sum of residues of tetracycline including oxytetracycline in uncooked edible tissues as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney for beef cattle, beef calves, non-lactating dairy cattle, and dairy calves (21 CFR 556.500(b)). The Acceptable Daily Intake for oxytetracycline is 25 micrograms per kilogram of body weight per day.

- **Withdrawal Time**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal time is at least 22 days prior to slaughter.

- **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 is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. 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 OXYTET 10 (oxytetracycline hydrochloride) Injection, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-452:
OXYTET 10 – Container Label; Box Label; Package Insert

Pioneer Labeling for NADA 108-963:
MEDAMYCIN-100 – Container Label; Package Insert