Date Approval: June 18, 2002

FREEDOM OF INFORMATION SUMMARY

Original Abbreviated New Animal Drug Application

Oxytetracycline injection
(200 mg/mL)

ANADA 200-306

Sponsored by:

Norbrook Laboratories, Ltd.
105 Armagh Road
Newry BT35 6PU
Northern Ireland

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	ANADA 200-306
Sponsor Name:	Norbrook Laboratories, Ltd. Northern Ireland
Established Name:	Oxytetracycline injection
Trade/Proprietary Name:	Oxytetracycline Injection 200 mg/mL
Dosage Form:	Sterile injectable solution
How Supplied:	100, 250 & 500 mL bottles
How Dispensed:	OTC
Amount of Active Ingredient:	200 mg of oxytetracycline per mL
Route of Administration:	Intramuscular in swine; intramuscular, subcutaneously, and intravenous in cattle
Species:	Beef cattle, dairy cattle, calves, including preruminating (veal) calves and swine
Pioneer Product/"Listed" Product:	Liquamycin® LA-200®; oxytetracycline injection; NADA 113-232; Pfizer, Inc.

2. INDICATION FOR USE:

Oxytetracycline Injection (200 mg/mL) is intended for use in the treatment of the following diseases in beef cattle, dairy cattle, calves, including preruminating (veal) calves and swine when due to oxytetracycline susceptible organisms.

CATTLE

Oxytetracycline Injection (200 mg/mL) is indicated in the treatment of the pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine *keratoconjunctivitis* (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresi*; leptospirosis caused by *Leptospira*

pomona; and wound infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

SWINE

In swine, Oxytetracycline Injection (200 mg/mL) is indicated in the treatment of the bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused *by Leptospira pomona.*

In sows, Oxytetracycline Injection (200 mg/mL) is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

3. DOSAGE:

CATTLE

Oxytetracycline Injection (200 mg/mL) is to be administered by intramuscular, intravenous or subcutaneous injection to beef cattle, dairy cattle, and calves, including preruminating (veal) calves.

A single dose of 9 mg of Oxytetracycline Injection (200 mg/mL) per pound of body weight administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

Oxytetracycline Injection (200 mg/mL) is to be administered by intramuscular, intravenous or subcutaneous injection at a level 3 to 5 mg of oxytetracycline per pound of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg per pound of body weight per day is recommended. Treatment should be continued 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

SWINE

A single doses of 9 mg of Oxytetracycline Injection (200 mg/mL) per pound of body weight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Oxytetracycline Injection (200 mg/mL) can also be administered by intramuscular injection at a level of 3 to 5 mg of oxytetracycline per pound of body weight per day. Treatment should be continued 24 to 48 hours following remission of diseases signs; however, not to

exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment

For sows, administer once intramuscularly 3 mg. of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb. of body weight and under, Oxytetracycline Injection (200 mg/mL) should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

4. 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. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADAs for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. 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, October, 2000).

Based upon the formulation characteristics of the generic product, Norbrook Laboratories, Ltd., was granted a waiver [dated April 13, 1994] from conducting an *in vivo* bioequivalence study for oxytetracycline injection. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

5. HUMAN FOOD SAFETY:

Tolerance

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows:

(a) 2 parts per million (ppm) in muscle
(b) 6 ppm in liver
(c) 12 ppm in fat and kidney

The ADI for total tetracycline residues is 25 micrograms per kilogram of body weight per day (21CFR 556.500).

Withdrawal time

The withdrawal times are those previously assigned to the pioneer product. The withdrawal time for oxytetracycline injection is established under 21 CFR 522.1660; 28 days for cattle and swine.

Regulatory Method for Residues

The analytical method for detection of residues of the drug is the cylinder plate microbiological test using Bacillus cereus var. mycoides (ATCC 11778) as outlined in the "Antibiotic Residues in Milk, Dairy Product and Animal Tissues: Methods, Reports, and Protocols" October 1968. National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204. (Copies available from FDA, Center for Veterinary Medicine, 7500 Standish Place, Rockville Maryland 20855).

6. 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 base (200 mg/mL) when used under the proposed conditions of use, is safe and effective for its labeled indications.

7. LABELING:

Attachments:

The generic Oxytetracycline Injection labeling and approved pioneer Liquamycin® LA-200® labeling.

Generic	**Pioneer**
100 mL & 250 mL – bottles –	100 mL & 250 mL – bottles –
500 mL – bottle – Oxytetracycline Injection	500 mL – bottle – Liquamycin LA-200
Package insert – Oxytetracycline Injection	Package insert – Liquamycin LA-200
Cartons	Cartons

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.