Date of Approval: June 13, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-128

Agrimycin®-200

Indications for use: For the treatment of various bacterial diseases in cattle and swine.

Sponsored by:

Agri Laboratories, Ltd.
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number	ANADA 200-128
b. Sponsor:	Agri Laboratories, Ltd. P.O. Box 3103 St. Joseph, MO 64503 Drug Labeler Code: 057561
c. Established Name:	Oxytetracycline dihydrate injection
d. Proprietary Name:	Agrimycin®-200
e. Dosage Form:	Injectable
f. How Supplied:	100, 250 & 500 ml bottles
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base as oxytetracycline dihydrate.
i. Route of Administration:	Intramuscularly, intravenously or subcutaneously
j. Species/Class:	Cattle and swine
k. Recommended Dosage:	Cattle: Administer subcutaneously or intravenously at 3 to 5 milligrams and subcutaneously at 9 milligrams of oxytetracycline per pound of body weight per day: 9 milligrams per pound of body weight as a single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical; 9 milligrams per pound of body weight as single dosage for treatment of infectious bovine keratoconjunctivitis.

Swine: administer intramuscularly at 3 to 5 milligrams of oxytetracycline per pound of body weight per day; intramuscularly at 9 milligrams per pound of body weight as a single dosage where re-treatment for pneumonia is impractical.

Sows: Administer once intramuscularly at 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

l. Pharmacological Category: Antibacterial

m. Indications: Beef cattle, dairy cattle, calves, including preruminating (veal) calves: indicated in the treatment of pneumonia and shipping fever complications 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: indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli;* pneumonia caused by *Pasteurella multocida;* and leptospirosis caused by *Leptospira pomona.* In sows, it is indicated as an aid in the control of

infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

n. Pioneer Product: Liquamycin® LA-200® Oxytetracycline
Pfizer, Inc., NADA 113-232

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 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, Agri Laboratories, Ltd. was granted a waiver on July 5, 1991, from the requirement of an *in vivo* bioequivalence study for Agrimycin®-200 Injection. The generic and pioneer products contain the same active and similar inactive ingredients and both are parenteral solutions. The pioneer product, Liquamycin® LA-200®, the subject of Pfizer's NADA 113-232, was approved on March 14, 1980.

3. HUMAN SAFETY:

Tolerance for Residues:

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef and dairy cattle, 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
(d) 0.3 ppm in milk

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. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

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.

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 Agrimycin®-200 (oxytetracycline hydrochloride), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Labeling:

Agrimycin®-200 labeling: 100, 250, 500 mL vials & insert

Liquamycin® LA-200® labeling: 250 mL vial & insert

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.