

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.

I. 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 lignieresii*; 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*.

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.