Approval Date: June 30, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-066

AGRIMYCIN 166
(oxytetracycline hydrochloride)

Additional packet size (9.87 oz [280 g]), change of strength of oxytetracycline HCl, new trade name and change in inactive ingredients

Sponsored by:

Agri Laboratories, Ltd.
P.O. Box 3103
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. General Information:

a. File Number:	ANADA 200-066
b. Sponsor:	Agri Laboratories, Ltd. P.O. Box 3103 St. Joseph, MO 64503 Drug Labeler Code: 057561
c. Established Name:	Oxytetracycline hydrochloride
d. Proprietary Name:	AGRIMYCIN 166
e. Dosage Form:	Soluble Powder
f. How Supplied:	9.87 oz [280 g] packet and 40 packets in a pail
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each 2.73 grams of powder contains 1 gram of oxytetracycline hydrochloride (packet: 9.87 oz [280 g]).
i. Route of Administration:	Oral
j. Species/Class:	Chickens, turkeys, & swine
k. Recommended Dosage:	Swine-10 mg per pound body weight daily for five days. Chickens-200-800 mg per gallon Turkeys-200-400 mg per gallon, for growing turkeys-25 mg per pound body weight daily
l. Pharmacological Category:	Antibacterial
m. Indications:	Chickens: 200 to 400 mg per gallon for control of infectious synovitis caused by *Mycoplasma synoviae,* susceptible to oxytetracycline.

400 to 800 mg per gallon for control of respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *Escherichia coli,* susceptible to oxytetracycline.
400 to 800 mg per gallon for control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.
Turkeys: 200 to 400 mg per gallon for control of Hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.
400 mg per gallon for control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.
25 mg/lb body weight in growing turkeys for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.
Swine: 10 mg/lb body weight for the control and treatment of the following diseases in swine – Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline. 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: OXYTET Soluble; oxytetracycline hydrochloride; NADA 130-435; Alpharma, Inc.

o. Effect of the Supplement: The supplement provides for approval of an additional packet size, 9.87 oz [280 g], a different trade name, an alternate concentration of active ingredient and a change in the inactive ingredients in the finished dosage form.

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 shows 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, Agri Laboratories, Ltd., was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product AGRIMYCIN-166. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredients. The pioneer product, OXYTET Soluble (oxytetracycline hydrochloride), sponsored by Alpharma, Inc., NADA 130-435, was approved on August 18, 1985.

3. HUMAN SAFETY:

· **Tolerances for Residues:**
The tolerances established for the pioneer product apply to the generic product.
Tolerances for the sums of residues of tetracycline, including oxytetracycline in tissues of swine, chickens, and turkeys are as follows: (a) 2 parts per million (ppm) in muscle; (b) 6 ppm in liver; (c) 12 ppm in fat and kidneys (21 CFR § 556.150). The acceptable daily intake for residues of oxytetracycline is 25 micrograms per kilogram of body weight per day.

· **Withdrawal Times:**
The assigned withdrawal period is the same as the pioneer product.
Based on the limitations in 21 CFR § 520.1660d, a zero day withdrawal time is required for chickens, turkeys, and swine.

· **Regulatory Methods for Residues:**
The regulatory analytical method for the determination of residue of oxytetracycline is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778). The method is found in *Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols*, Revised October, 1968, Reprinted December, 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

4. AGENCY CONCLUSIONS:

This supplemental 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-166 (oxytetracycline hydrochloride), 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 indicated below:

Generic Labeling for ANADA 200-066:
9. 87 oz packet label & 40 X 9.87 oz pail label

Pioneer Labeling for NADA 130-435:
9.87 oz packet label