DATE OF APPROVAL LETTER: OCT 4 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-066

AGRIMYCIN® 343 (oxytetracycline HCl)

"revised withdrawal period for turkeys and swine"

Sponsored by Agri Laboratories, Ltd.

I. GENERAL INFORMATION:

ANADA: 200-066

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

Generic Name: Oxytetracycline HCl

Trade Name: AGRIMYCIN® 343 SOLUBLE POWDER

Marketing Status: OTC

Effect of the Supplement: Revised withdrawal period for turkeys and swine.

II. INDICATIONS AND DOSAGES FOR USE:

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. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona,* susceptible to oxytetracycline.

III. DRUG EFFECTIVENES AND TARGET ANIMAL SAFETY:

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. ANADA's 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 10, 2000).

Based upon the formulation characteristics of the generic product, AGRIMYCIN® 343 was granted a waiver from conducting an *in vivo* bioequivalence study and approved on July 15, 1994. The generic and pioneer products contain the same active and inactive ingredients and are soluble powders.

IV. HUMAN FOOD SAFETY:

A. TOLERANCES

Tolerances are established in 21 CFR 556.500 for the sum of residues in tissues of swine and turkeys as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney. The acceptable daily intake (ADI) for total oxytetracycline residues is 25 micrograms per kilogram of body weight per day.

B. WITHDRAWAL TIME:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for pioneer oxytetracycline soluble powders (NADA 130-435, Alpharma, Inc,'s Oxytet Soluble®) is established under 21 CFR 520.1660d. Alpharma, Inc. received approval on November 29, 2000, for a zero day withdrawal time for turkeys and swine. This supplemental ANADA requests the same zero-day withdrawal period for turkeys and swine based on the waiver

granted to the original approval of Agri Laboratories, Ltd.'s ANADA. No new data were required for the reduced withdrawal times in swine and turkeys.

C. REGULATORY METHODS

The regulatory method for determination of oxytetracycline in tissues is a microbiological assay procedure using *Bacillus cereus* var. *mycoides* (ATCC 11778) suspension and is found in the FDA publication "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols" revised October 1968, reprinted December 1974.

V. AGENCY CONCLUSIONS

This supplemental ANADA satisfies the requirements of section 512 of the Federal Food, Drug and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) to demonstrates that AGRIMYCIN® 343 (oxytetracycline HCl), is safe and effective for use in turkeys and swine for the approved indications, when administered in water at the approved dose.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity.

VI. APPROVED PRODUCT LABELING (attached)

A. Pioneer Facsimile label – OXYTET Soluble 3.09 lbs (1400 g)
B. Generic Facsimile labels – AGRIMYCIN® 343 - 50 packets 4.78 oz (135.5g)
AGRIMYCIN® 343 - 5 lbs (2.27 kg).

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) 827-6500.