

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-066

B. Sponsor

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

C. Proprietary Name

Agrimyn™-343 Soluble Powder

D. Established Name

oxytetracycline hydrochloride

E. Dosage Form

Soluble powder

F. Amount of Active Ingredient

Each packet contains 102.4 grams of OTC HCl

G. How Supplied

4.78 oz packets, 50 packets/bucket

H. Dispensing Status

OTC

I. Dosage Regimen and Indications

CHICKENS – INDICATIONS

Control of infectious synovitis caused by *Mycoplasma synoviae*
DOSAGE: 200-400 mg/gal

Control of chronic respiratory disease (CRD) and air sac infection caused by
Mycoplasma gallisepticum and *Escherichia coli*
DOSAGE: 400-800-mg/gal

Control of fowl cholera caused by *Pasteurella multocida*
DOSAGE: 400-800-mg/gal

TURKEYS- INDICATIONS

Control of Hexamitiasis caused by *Hexamita meleagridis*

DOSAGE: 200-400 mg/gal

Control of infectious synovitis caused by *Mycoplasma synoviae*

DOSAGE: 400 mg/gal

Growing turkeys: Control of body weight complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)

DOSAGE: 25 mg/lb

SWINE – INDICATIONS

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.

DOSAGE: 10 mg/lb body weight

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

DOSAGE: 10 mg/lb body weight

GENERAL DIRECTIONS

Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis or advice on dosage for chickens or turkeys. As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys.

J. Route of Administration

Administer orally in drinking water

K. Species/Class

Chickens, Turkeys, and Swine

L. Reference Listed New Animal Drug

Oxytet Soluble; oxytetracycline HCl; NADA 130-435; I.D. "Listed" Product: Russell.

M. Date of Approval

July 15, 1994

II. 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. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. 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, April 1990).

Based upon the formulation characteristics of the genetic product, Agri Laboratories Ltd. was granted a waiver from conducting an *in vivo* bioequivalence study for Oxytetracycline HCl Soluble Powder. The genetic and pioneer products contain the same active ingredient and are water soluble powders administered as oral solutions. The genetic product contains no inactive ingredients that may significantly affect the absorption of the active ingredient.

III. HUMAN FOOD SAFETY

Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances of 3 ppm in uncooked kidney and 1 ppm in uncooked muscle, liver, fat, and skin are established for residues of oxytetracycline in chickens and turkeys under 21 CFR 556.500(a). A tolerance of 0.1 ppm in uncooked edible tissues is established for residues of oxytetracycline in swine under 21 CFR 556.500(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.

For oxytetracycline powder, a withdrawal period of zero has been established for chickens. A withdrawal period of 5 days is established for turkeys [21 CFR 520.1660(d)]. Oxytetracycline HCl soluble powder is not to be administered to chickens or turkeys producing eggs for human consumption. A withdrawal period of 13 days is established for swine [21 CFR 520.1660(d)].

Regulatory Method:

The analytical method for the determination of oxytetracycline in tissues uses a microbiological assay procedure. This method is found in the *Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols*, revised October 1968, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

IV. 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 hydrochloride when used under the proposed conditions of use, is safe and effective for its labeled indications.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.