Date of Approval: June 2, 2006

FREEDOM OF INFORMATION SUMMARY

ANADA 200-305

ORIGINAL ABBERVIATED NEW ANIMAL DRUG APPLICATION

Oxytetracycline Hydrochloride Soluble Powder

Oxytetracycline hydrochloride

For the treatment of bacterial disease in chickens, turkeys, and swine

Sponsored by:

Vétoquinol N.-A., Inc.

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1. GENERAL INFORMATION:

a.	File Number:	ANADA 200-305
b.	Sponsor:	Vétoquinol N.-A., Inc. 2000 chemin Georges Lavaltrie (PQ), Canada J5T 3S5 Drug Labeler Code: 059320
c.	Established Name:	Oxytetracycline hydrochloride
d.	Proprietary Name:	Oxytetracycline hydrochloride soluble powder
e.	Dosage Form:	Oral powder
f.	How Supplied:	280 g and 560 g packets and 2.27 kg pail
g.	How Dispensed:	OTC
h.	Amount of Active Ingredients:	102.4 g or 204.8 g of oxytetracycline per packet, or 830.2 g of oxytetracycline per pail.
i.	Route of Administration:	Oral in drinking water
j.	Species/Class:	Chickens, turkeys, and swine
k.	Recommended Dosage:	Chickens For control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to oxytetracycline: 200-400 mg For control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *Escherichia coli* and fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline: 400-800 mg Turkeys For control of hexamitiasis caused by *Hexamita meleagridis*, susceptible to oxytetracycline: 200-400 mg For control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to

oxytetracycline: 400 mg

- In growing turkeys, for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline: 25 mg/lb body weight

Swine

For control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline: 10 mg/lb body weight

In breeding swine, for Leptospirosis (reducing the incidence of abortion and shedding of leptospira) caused by *Leptospira pomona*, susceptible to oxytetracycline: 10 mg/lb body weight.

l.	Pharmacological Category:	Antimicrobial
m.	Indications:	For the treatment of bacterial diseases in chickens, turkeys, and swine.
n.	Pioneer Product:	OXYTET Soluble (oxytetracycline hydrochloride); NADA 130-435; Alpharma, Inc.

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 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 Guidance, revised October 09, 2002).

Based on the formulation characteristics of the generic product Vétoquinol N.-A., Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Oxytetracycline Hydrochloride Soluble Powder. The generic product is administered as an oral solution in drinking water, contains the same active ingredients 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 ingredient. The pioneer product, OXYTET Soluble (oxytetracycline hydrochloride), the subject of Alpharma, NADA 130-435, was approved on August 14, 1985.

3. HUMAN SAFETY:

- **Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product. A tolerance of the following is established for tetracycline residues in the uncooked edible tissue of turkeys, chickens, and swine under 21 CFR 556.500:

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 Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.
The withdrawal times are as follows:

a) Turkeys: Do not use in birds producing eggs for human consumption. Withdraw 0 days prior to slaughter.
b) Chickens: Do not use in birds producing eggs for human consumption. Withdraw 0 days prior to slaughter.
c) Swine: Withdrawal time is 0 days prior to slaughter.

- **Regulatory Method for Residues:**

The analytical method for detection of residues in tissues is a microbiological test using *Bacillus cereus var mycoides* (ATCC 11778). This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Oxytetracycline Hydrochloride Soluble Powder, when used under its proposed conditions of use, is safe and effective for its labeled indications.

ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Generic animal drug labeling for ANADA 200-305
Oxytetracycline Hydrochloride Soluble Powder
280 g packet
560 g packet
2.27 kg pail

Pioneer animal drug labeling
OXYTET Soluble
25.6 g packet
102.4 g packet
512 g packet
648 g packet