Date of Approval Letter: December 28, 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-123

MAXIM - 200®

(Oxytetracycline)

Addition of subcutaneous route of administration for beef cattle, nonlactating dairy cattle, and preruminating (veal) calves

Sponsored by

PHOENIX SCIENTIFIC, INC.

1. GENERAL INFORMATION

a. File Number:	200-123
b. Applicant:	Phoenix Scientific, Inc. P. O. Box 6457 St. Joseph, Missouri 64506-0457 Drug Labeler Code: 059130
c. Established Name:	oxytetracycline injection
d. Trade/Proprietary Name:	MAXIM - 200®
e. Dosage Form:	Sterile injectable solution
f. How Supplied:	100, 250 and 500 mL bottles
g. How Dispensed:	OTC
h. Amount of Active Ingredient:	200 mg/mL
i. Route of Administration:	Intramuscular in swine; subcutaneous, intramuscular, or intravenous in cattle
j. Species:	Beef cattle, non-lactating dairy cattle, preruminating (veal) calves, and swine
k. Recommended Dose:	For Cattle: 3-5 mg/lb body weight IM, SC, or IV once daily for up to 4 days, or 9 mg/lb IM or SC
l. Pharmocological Category:	Antimicrobial
m. Indications:	In cattle, it is indicated for the treatment of pneumonia and shipping fever complex 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 infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. In swine, it is indicated for 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.*
n. Pioneer Product/ "Listed" Product:	LIQUAMYCIN® LA-200; oxytetracycline injection; NADA # 113-232; Pfizer
o. Effect of Supplement:	To add subcutaneous route of administration for cattle.

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 data, drug 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 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, 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc., was granted a waiver from conducting an *in vivo* bioequivalence study for oxytetracycline injection. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

3. HUMAN FOOD SAFETY:

- **Tolerances for Residues:**
  The tolerances established for the pioneer product apply to the generic product. Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, of 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney under 21 CFR 556.500.

- **Withdrawal Time:**
  Under the CVM Bioequivalence Guidelines, when a generic product is granted a waiver of *in vivo* bioequivalence testing, the withdrawal period established for the pioneer product is also assigned to the generic product.

  For MAXIM - 200®, oxytetracycline injection, a withdrawal period of 28 days has been established for beef cattle, nonlactating dairy cattle, preruminating (veal) calves, and swine (21 CFR 522.1660).

- **Regulatory Method for Residues:**
  The analytical method for detection of MAXIM - 200® in tissues is the cylinder plate microbiological test using Bacillus *cereus* var. *mycoides* (ATCC 11778) as outlined in the "Antibiotic Residues in Milk, Dairy Products 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 MAXIM - 200® when used under the proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile bottle label and insert for MAXIM - 200®, oxytetracycline injection 200 mg/mL, 100, 250 and 500 mL bottles