Approval letter dated: November 19, 2002

**FREEDOM OF INFORMATION SUMMARY**

# SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

# ANADA 200-123

## MAXIM-200® Injection

"addition for use in lactating dairy cattle"

Sponsored by:

Phoenix Scientific, Inc.
St. Joseph, MO 64503

# FREEDOM OF INFORMATION SUMMARY

## 1. GENERAL INFORMATION:

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| ANADA Number: | 200-123 |
| Sponsor: | Phoenix Scientific, Inc.<br>3915 S. 48th St. Terrace<br>St. Joseph, MO 64503<br><br>Drug Labeler Code: 059130 |
| Generic Name: | Oxytetracycline Hydrochloride, USP |
| Pioneer Product: | Pfizer, Inc., Liquamycin® LA-200<br>NADA 113-232 |
| Trade Name: | MAXIM-200® Injection |
| Dosage Form: | Injectable |
| Effect of Supplement: | The supplement provides for use in lactating dairy cattle. |
| Route of Administration: | Intramuscular in swine, Intramuscular, Intravenous, and Subcutaneous in cattle |

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| Dosage & Indications for Use: | Cattle: Beef and dairy, calves including pre-ruminating veal calves.<br>For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* 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.<br><br>Swine:<br>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.*<br><br>Dosage 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 as a single dose.<br><br>Dosage For Swine: 3-5 mg/lb body weight IM daily, or 9 mg/lb IM as a single dose. |

## 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 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 2000).

Based upon the formulation characteristics of the generic product, MAXIM-200® Injection was granted a waiver on October 22, 1993, from conducting an *in vivo* bioequivalence study. The abbreviated new animal drug application was approved on February 10, 1995. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

## 3. HUMAN SAFETY

The previous withdrawal periods and tolerances remain unchanged. Therefore, no human food safety information is required.

Withdrawal periods: Cattle & Swine 28 days

REGULATORY METHOD:

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. (Available from the FDA, Center for Veterinary Medicine, 7500 Standish Place, Rockville, Maryland 20855.)

## 4. **AGENCY CONCLUSIONS**:

This Supplemental Abbreviated New Animal Drug Application (ANADA) filed 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® Injection is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. **LABELING:**

Attachments:

Generic Labeling:
Package Insert
100, 250, & 500 mL bottles

Pioneer Labeling:
Package Insert
100, 250, & 500 mL bottles

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) 827-6567.