Approval Date: February 10, 1995

# FREEDOM OF INFORMATION SUMMARY

## I. GENERAL INFORMATION

### A. File Number

ANADA 200-123

### B. Sponsor

Phoenix Scientific, Inc.
P.O. Box 6457
St. Joseph, Missouri 64506-0457

### C. Proprietary Name

Maxim 200

### D. Established Name

oxytetracycline

### E. Dosage Form

Sterile injectable solution

### F. Dispensing Status

OTC

### G. Route of Administration

Intramuscular or intravenous

### H. Indication

Maxim 200 is intended for use in the treatment of the following diseases in beef cattle, nonlactating dairy cattle and swine when due to oxytetracycline susceptible organisms.

## II. EFFECTIVENESS AND 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. 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 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.

## III. HUMAN FOOD SAFETY

### A. Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 ppm is established for the uncooked edible tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, and 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. The withdrawal time for oxytetracycline injection is established under 21 CFR 522.1660: 28 days for beef cattle, nonlactating dairy cattle, and swine.

### C. Regulatory Method for Residues

The analytical method for detection of residues of the drug 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.

## 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 injection 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.