Approval Date: May 8, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-154

B. Sponsor

Pennfield Oil Co
14040 Industrial Road
Omaha, Nebraska 68144

C. Proprietary Name

Oxytetracycline 200

D. Established Name

oxytetracycline injection

E. Dosage Form

Sterile injectable solution

F. Amount of Active Ingredient

200 mg/mL

G. How Supplied

500 mL bottles

H. Dispensing Status

OTC

I. Dosage Regimen

CATTLE

- Oxytetracycline 200 is to be administered by intramuscular or intravenous injection to beef cattle and non-lactating dairy cattle.

- A single dose of 9 mg of Oxytetracycline 200 per pound of body weight administered intramuscularly is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

- Oxytetracycline 200 can also be administered by intravenous or intramuscular injection at a level of 3 to 5 mg of oxytetracycline per pound of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg per pound of body weight per day is recommended. Treatment should be continued 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

SWINE

- A single dose of 9 mg of Oxytetracycline 200 per pound of body weight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

- Oxytetracycline 200 can be administered by intramuscular injection at a level of 3 to 5 mg of oxytetracycline per pound of body weight per day. Treatment should be continued 24 to 48 hours following remission of diseases signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

- For sows, administer once intramuscularly 3 mg of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

- For swine weighing 25 lb of body weight and under, Oxytetracycline 200 should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

J. Route of Administration

Intramuscular in swine, intramuscular or intravenous in cattle

K. Species/Class

Beef cattle, non-lactating dairy cattle, and swine

L. Indication

Oxytetracycline 200 is intended for use in the treatment of the following diseases in beef cattle, non-lactating dairy cattle and swine when due to oxytetracycline susceptible organisms:

CATTLE

- Oxytetracycline 200 is indicated in 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 lignieresi*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

SWINE

- In swine, Oxytetracycline 200 is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*.

- In sows, Oxytetracycline 200 is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

M. Reference Listed New Animal Drug

Liquamycin® LA-200; oxytetracycline injection; NADA #113-232; Pfizer

II. EFFECTIVENESS AND TARGET 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, Pennfield Oil Company 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

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.

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.

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.