Approval letter dated: Jan. 12, 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

ANADA 200-154

Pennox™ 200 Injectable

An injectable antibiotic for the treatment of
bacterial diseases in swine and cattle.

Sponsored by:

Pennfield Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	200-154
Original Approval Date:	May 8, 1996
Sponsor:	Pennfield Oil Company 14040 Industrial Road Omaha, NE 68144
Generic Name:	Oxytetracycline Hydrochloride, USP
Pioneer Product:	Pfizer Inc., NADA 113-232, Liquamycin® LA-200
Trade Name:	Pennox™ 200 Injection
Dosage Form:	Injectable
How Supplied:	500 mL bottles
How Dispensed:	OTC
Amount of Active Ingredients:	Each ml contains 200 mg of oxytetracycline per mL
Route of Administration:	Intramuscular in swine, Intramuscular, Intravenous and Subcutaneous (new) in cattle
Species:	Swine, cattle, calves, including pre-ruminating (veal) calves (new)
Indications for Use:	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.

Swine:
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.*

Effect of Supplement: The supplement provides for the addition of the subcutaneous administration of oxytetracycline injectable solution in beef cattle, non-lactating dairy cattle, and calves, including pre-ruminating (veal) calves.

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 (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). Pennfield Oil Company is supplementing their ANADA for the addition of the subcutaneous administration of oxytetracycline injectable solution in beef cattle, nonlactating dairy cattle, and calves, including pre-ruminating (veal) calves. Based upon the formulation characteristics of the generic product, Pennfield Oil Company was granted a waiver on from conducting an *in vivo* bioequivalence study with Oxyteracycline 200 Hydrochloride Injectable. The generic product was approved on May 8, 1996. The three-year exclusivity period for the additional claims granted to the pioneer product ended on April 23, 2000. Pennfield Oil Company is supplementing their approved generic product for the additional claims mentioned above. No new data was required for the additional new claims.

3. HUMAN FOOD SAFETY

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

4. AGENCY CONCLUSION:

This is a Supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), these are Category II changes providing for the addition of a new route of administration and a new class of cattle. The approval of these changes is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Attachment:

Generic and pioneer facsimile labeling