Approval letter dated: June 13, 2002

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-154

Pennox 200 Injection

"addition for use in lactating dairy cattle"

Sponsored by:

Pennfield Oil Company
Omaha, Nebraska 68144

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	200-154
Sponsor:	Pennfield Oil Company 14040 Industrial Road Omaha, Nebraska 68144 Drug Labeler Code: 053389
Generic Name:	Oxytetracycline Hydrochloride, USP
Pioneer Product:	Pfizer, Inc., Liquamycin® LA-200 NADA 113-232
Trade Name:	Pennox 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

Indications for Use:	Cattle: Beef and dairy, calves including pre-ruminating veal calves. 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.*

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). 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. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADAs for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period.

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, October 10, 2000).

Based upon the formulation characteristics of the generic product, PENNOX 200 Injection was granted a waiver from conducting an *in vivo* bioequivalence study. The abbreviated new animal drug application was approved on May 8, 1996. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

3. HUMAN FOOD 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 Pennox 200 Injection is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. **LABELING:**

Attachments:

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

Generic Labeling:
Package Insert
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.