Date approval letter: April 10, 2002

FREEDOM OF INFORMATION SUMMARY

Supplemental Abbreviated New Animal Drug Application
ANADA 200-026

"Revised withdrawal period in swine"

Pennox™ 343 (Oxytetracycline hydrochloride)

PennField Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

SUPPLEMENTAL FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION **ANADA 200-026**

PennField Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

a. Established Name:	Oxytetracycline hydrochloride
b. Trade Name/Proprietary Name:	Pennox™ 343
c. Dosage Form:	Soluble Powder for drinking water
d. How Supplied:	4.78 oz packets and 23.9 oz packets
e. How Dispensed:	OTC
f. Amount of Active Ingredients:	Each packet contains oxytetracycline hydrochloride equivalent to 102.4 grams or 512 grams
g. Species:	Swine
h. Labeled Dosage and Indications:	Swine 10 milligrams per pound of body weight daily. For the control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: Control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona* susceptible to oxytetracycline.
i. Effect of the Supplement:	Revised withdrawal period (0-day) in swine
j. Pioneer Product "Listed" Product:	Terramycin® Soluble Powder, NADA 8-622

II. DRUG EFFECTIVENES 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. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's 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, PennField Oil Co. was granted a waiver from conducting an *in vivo* bioequivalence study and approved on March 13, 1997. The generic and pioneer products contain the same active and inactive ingredients and are soluble powders.

III. HUMAN FOOD SAFETY:

A. TOLERANCES:

Tolerances are established in 21 CFR 556.500 for the sum of residues in tissues of swine as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney. The acceptable daily intake (ADI) for total oxytetracycline residues is 25 micrograms per kilogram of body weight per day.

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 pioneer oxytetracycline soluble powder (NADA 8-622, Pfizer, Inc.'s Terramycin 343®) is established under 21 CFR 520.1660d. Pfizer, Inc. received approval on April 25, 2001, for a zero day withdrawal time for swine. This supplemental ANADA requests the same zero-day withdrawal period for swine based on the waiver granted to the original approval of PennField's ANADA. No new data were required for the reduced withdrawal time in swine.

C. REGULATORY METHODS:

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.

IV. Agency Conclusions:

This supplemental ANADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) which demonstrates that PENNOX™ 343 (oxytetracycline HCl), is safe and effective for use in swine for the approved indications, when administered in water at the approved dose.

Tolerances are established in 21 CFR 556.500 for the sum of residues in tissues of swine as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney. The preslaughter withdrawal times for swine are zero days. The acceptable daily intake (ADI) for total oxytetracycline residues is 25 micrograms per kilogram of body weight per day.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. APPROVED PRODUCT LABELING (attached)

A. Pioneer Facsimile label –

Terramycin® 24.8 lb

Terramycin® 343 4.78 oz, 9.55 oz, & 4.5 lb

B. Generic Facsimile labels –

Pennox™ 343 4.78 oz & 23.9 oz