Approval Date: March 15, 1988

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 140-582

B. Sponsor

Anthony Products Co.
5600 Peck Rd.
Arcadia, CA 91006

C. Proprietary Name

Oxytetracycline Hydrochloride Injection, 50 mg and 100 mg

D. Established Name

oxytetracycline HCl

E. Dosage Form

Oxytetracycline HCl Injection (50 mg/ml and 100 mg/ml) is available in 500 ml and 100 ml multidose vials containing 50 mg or 100 mg Oxytetracycline Hydrochloride per milliliter.

F. Route of Administration

Intravenous

G. Indication

Oxytetracycline HCl (50 mg and 100 mg) is intended for use in the treatment of the following diseases in beef cattle and non-lactating dairy cattle when due to oxytetracycline-susceptible organisms:

Cattle:

In cattle, Oxytetracycline (50 mg and 100 mg) is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; 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.

If the product contains the statement "Federal law restricts this drug to use by or on the order of a licensed veterinarian," it may contain additional directions for use in beef cattle and non-lactating dairy cattle for the treatment of anaplasmosis caused by Anaplasma marginale and anthrax caused by *Bacillus anthracis*.

II. EFFECTIVENESS

An in-vitro equivalence of biological activity was conducted using the microbiological method of potency testing as described in USP XXI and comparing this biological activity with that of the Pfizer product for both the 50 mg/ml and the 100 mg/ml products. The pioneer NAS/NRC/DESI product (Pfizer) is cited in 21 CFR 522.1662a(c)(1). These conditions are NAS/NRC/DESI reviewed and deemed safe and effective. Applications for these uses need not include effectiveness data as specified by 21 CFR 514.111. However, satisfactory bioequivalency data were submitted in support of this approval. The Anthony and Pfizer 50 mg/ml products were tested and found to contain 50.4 - 53.8 and 52.4 -55.5 mg/ml oxytetracycline HCl, respectively. The 100 mg/ml generic and Pfizer products were assayed and found to contain 100.5 - 105.5 and 108.3 and 113.4 mg/ml of oxytetracycline HCl,respectively. This data is satisfactory and meets our requirements for the establishment of bioequivalency. Since the drug is indicated for intravenous use only, the drug is introduced directly into the blood stream and the bioavailability of thedrug is therefore assured.The safety and efficacy data upon which this application was approved are found in NADAs 10-918 and 11-948 for Elanco Products Co., and are summarized in an FOI Summary filed with the Dockets Management Branch (HFA-305) under the generic name of the drug.

III. HUMAN FOOD SAFETY

The formulations for the 50 mg/ml and the 100 mg/ml drug products have been evaluated and found chemically and microbiologically equivalent to the pioneer 100 mg/ml product. Therefore, since the products are both chemically and microbiologically equivalent and the fact that the products are indicated for intravenous use only assuring biological equivalence with 100 mg/ml the pioneer product, the 19-day withdrawal period for the pioneer product has been assigned to these products. Tissue residue data are not necessary.

IV. AGENCY CONCLUSIONS

The data submitted in support of this new animal drug application comply with the requirements of 512 of the Act and demonstrate that Oxytetracycline Injection 50 mg/ml and 100 mg/ml when used under its proposed condition of use are safe and effective for labeled indications.

Approval of the application poses no increased human risk from exposure to residues of oxytetracycline because the number of food producing animals receiving medication will not significantly increase and because the drug is already regulated at the requested use level.

The prescription (Rx) and over-the-counter (OTC) status is the same as the pioneer's. Therefore, this product is approved as an over the counter product as well as a prescription product.

The format of this FOI Summary document has been modified from its original form toconform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.