Approval Date: May 30, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 095-143

B. Sponsor

Pfizer Inc.
Exton, PA 19341

C. Proprietary Name

OXTC 10, 30, 50, 50-S, 100, 100-S, 100MR, 200

D. Established Name

oxytetracycline dihydrate pre-mix

E. Dosage Form

Type A Medicated article

F. Dispensing Status

OTC

G. Route of Administration

Oral

H. Dosage and Indication

CHICKENS

Dose	Indication
10-50 g/t	For broiler/fryer chickens: for an increased rate of weight gain and improved feed efficiency. (Use continuously)
100-200 g/t	Control of infectious synovitis caused by Mycoplasma synoviae; control of fowl cholera caused by Pasteurella multocida sensitive to oxytetracycline. (Feed continuously for 7 to 14 days)
400 g/t	Control of chronic respiratory disease (CRD) and air sac infection caused by Mycoplasma gallisepticum and Escherichia coli susceptible to oxytetracycline. (Feed continuously for 7 to 14 days) WARNING: Zero-day withdrawal period. In low calcium feeds, withdraw 3 days before slaughter. Do not administer to chickens producing eggs for human consumption.
500 g/t	Broiler chickens: Reduction of mortality due to air sacculitis (air-sac-infection) caused by Escherichia coli susceptible to oxytetracycline. (Feed for 5 days) WARNING: 24 hours withdrawal period. In low calcium feeds withdraw 3 days before slaughter. Do not administer to chickens producing eggs for human consumption.

TURKEYS

Dose	Indication
10-50 g/t	For growing turkeys: For an increased rate of weight gain and improved feed efficiency. (Use continuously)
200 g/t	Control of infectious synovitis caused by Mycoplasma synoviae susceptible to oxytetracycline. (Feed continuously for 7 to 14 days)
100 g/t	Control of hexamitiasis caused by Hexamita meleagrides susceptible to oxytetracycline. (Feed continuously for 7 to 14 days)
25 mg/lb body weight daily	Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline. (Feed continuously for 7 to 14 days) WARNING: At 200 g/ton use level or higher, withdraw 5 days before slaughter. Zero-day withdraw period for lower use levels. Do not administer to turkeys producing eggs for human consumption.

SWINE

Dose	Indication
10-50 g/t	For an increased rate of weight gain and improved feed efficiency. (Use continuously)
10 mg/lb	Treatment of bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis susceptible to oxytetracycline and control of bacterial pnuemonia caused by Pasteurella multocida susceptible to oxytetracycline. (Feed continuously for 7 to 14 days)
10 mg/lb	For breeding swine: Leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by Leptospira pomona susceptible to oxytetracycline. (Feed continuosly for 14 days) WARNING: 5 days withdrawal at 10mg/lb dosage.

CALVES, BEEF CATTLE and NONLACTATING DAIRY CATTLE

Dose	Indication
0.05 - 0.1 mg/lb For calves (up to 250 lbs)	For an increased rate of weight gain and improved feed efficiency. (Use continuously)
25 mg/head/day For calves (250-400 lbs)	For an increased rate of weight gain and improved feed efficiency. (Use continuously)
75 mg/head/day For growing cattle (over 400 lbs)	For an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses. (Use continuously)
0.5-2.0 g/head/day	For the prevention and treatment of the early stages of the shipping fever complex. (Feed 3- 5 days before and after arrival in feedlots.)
10 mg/lb	For the treatment of bacterial enteritis caused by Escherichia coli and bacterial pneumonia (shipping fever complex) caused by Pasteurella multocida susceptible to oxytetracycline. (Feed continuously for 7 to 14 days) WARNING: 5 days withdrawal at 10 mg/lb dosage. When used in milk replacers, the treatment claim (10 mg/lb) is limited to bacterial enteritis caused by Escherichia coli only.

SHEEP

Dose	Indication
10-20 g/t	For an increased rate of weight gain and improved feed efficiency. (Use continuously)
10 mg/lb	Treatment of bacterial enteritis caused by Escherichia coli and bacterial pneumonia caused by Pasteurella multocida susceptible to oxytetracycline. (Feed continuously for 7 to 14 days) WARNING: 5 days withdrawal at 10 mg/lb dosage.

HONEY BEES

Dose	Indication
200 mg/colony	For control of American Foulbrood caused by Bacillus larvae, and European Foulbrood caused by Streptococcus pluton susceptible to oxytetracycline. WARNING: Remove at least 6 weeks prior to main honey flow.

II. EFFECTIVENESS

The drug was the subject of National Academy of Science/National Research Council (NAS/NRC) reports which were published in the FEDERAL REGISTER of May 5, 1970 (FR 70-5446) and a final rule dated March, 1996, amended the animal regulations (1) to indicate that the pioneer product, NADA 8-804, Oxytetracycline Type A medicated article was DESI-finalized and (2) to specify the conditions of use for which appproval of similiar products need not include certain types of efficacy data, but require submission of bioequivalency or similiar data.

Pfizer's NADA 95-143 was submitted and reviewed prior to the 1988 implementation of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) and was designated the DESI "me-too" status for approval purposes. Pfizer's product has been shown to be comparable to the pioneer product, Oxytetracycline Type A Medicated Article.

III. TARGET ANIMAL SAFETY

Demonstration of comparability to the pioneer product established safety to the target animals.

IV. HUMAN FOOD SAFETY

Demonstration of comparability to the pioneer product established that this product will carry the same withdrawal periods for all the species and the same tolerances.

V. AGENCY CONCLUSIONS

This original NADA satisfies the requirements of section 512 of the Act and demonstrates that Oxytetracycline Type A Medicated Article when used under its proposed conditions of use, is safe and effective for the labeled indications. The approval provides for use of OxytetracyclineType A Medicated Article for the control and treatment of specific diseases in swine, calves, cattle, chickens, turkeys, and sheep and honey bees.

When NADA 95-143 was reviewed under NAS/NRC/DESI program, it was an over-the-counter product and this marketing status remains unchanged. Other Oxytetracycline Type A Medicated Articles for use in food-producing animals are also currently on the

market as over-the-counter products. Therefore, the Center for Veterinary Medicine has concluded that this product should retain over-the-counter marketing status.

Under the Generic Animal Drug and Patent Term Restoration Act of 1988, this approval does not qualify for an exclusivity period under section 512(c)(2)(F)(ii) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360b (c)(2)(F)(ii)) because the application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and in the case of food producing animals human food safety studies (other than bioequivalency or residue studies) essential to the approval were conducted or sponsored by PennField Oil.

VI. ATTACHMENTS

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) 443-2414.

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.