Date Approval____Feb. 12, 1999

FREEDOM OF INFORMATION SUMMARY

Abbreviated New Animal Drug Application

Oxytetracycline injection
GEOMYCIN 200

ANADA 200-232

Sponsored by:

PLIVA, d.d.
Ulica grada Vukovara 49
10000 Zagreb, CROATIA

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	ANADA 200-232
Sponsor Name:	PLIVA, d.d. Ulica grada Vukovara 49 10000 Zagreb, CROATIA
Established Name:	Oxytetracycline injection
Trade/Proprietary Name:	GEOMYCIN 200
Dosage Form:	Sterile injectable solution
How Supplied:	100 mL bottles and 500 mL bottles
How Dispensed:	OTC
Amount of Active Ingredient:	200 mg/mL
Route of Administration:	Intramuscular in swine, intramuscular or intravenous in cattle
Species:	Beef cattle, non-lactating dairy cattle, and swine
Pioneer Product/"Listed" Product:	Liquamycin® LA-200®; oxytetracycline injection; NADA 113-232; Pfizer

2. INDICATION FOR USE:

GEOMYCIN 200 (Oxytetracycline Injection) is intended for use in the treatment of the following diseases in beef cattle, nonlactating dairy cattle and swine when due to oxytetracycline susceptible organisms.

CATTLE

GEOMYCIN 200 (Oxytetracycline Injection) is indicated in the treatment of the pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* 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 lignieresi*; leptospirosis caused by *Leptospira pomona*; and wound infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

SWINE

In swine, GEOMYCIN 200 (Oxytetracycline Injection) is indicated in the treatment of the bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused *by Leptospira pomona.*

In sows, GEOMYCIN 200 (Oxytetracycline Injection) is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

3. DOSAGE

CATTLE

GEOMYCIN 200 (Oxytetracycline Injection) is to be administered by intramuscular or intravenous injection to beef cattle and nonlactating dairy cattle.

A single dose of 9 mg of GEOMYCIN 200 (Oxytetracycline Injection) per pound of body weight administered intramuscularly is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

GEOMYCIN 200 (Oxytetracycline Injection) is to be administered by intramuscular or intravenous injection at a level 3 to 5 mg of oxytetracycline per pound of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg per pound of body weight per day is recommended. Treatment should be continued 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hour of the beginning of treatment.

SWINE

A single doses of 9 mg of GEOMYCIN 200 (Oxytetracycline Injection) per pound of body weight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

GEOMYCIN 200 (Oxytetracycline Injection) can also be administered by intramuscular injection at a level of 3 to 5 mg of oxytetracycline per pound of body weight per day. Treatment should be continued 24 to 48 hours following remission of diseases signs;

however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment

For sows, administer once intramuscularly 3 mg. of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb. of body weight and under, GEOMYCIN 200 (Oxytetracycline Injection) should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

4. EFFECTIVENESS AND BIOEQUIVALENCY:

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. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. 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, April 1990).

Based upon the formulation characteristics of the generic product, PLIVA d.d. , was granted a waiver from conducting an *in vivo* bioequivalence study for oxytetracycline injection. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

5. HUMAN FOOD SAFETY

Tolerance

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows:

(a) 2 parts per million (ppm) in muscle
(b) 6 ppm in liver
(c) 12 ppm in fat and kidney

Withdrawal Time

The withdrawal times are those previously assigned to the pioneer product. The withdrawal time for oxytetracycline injection is established under 21 CFR 522.1660; 28 days for beef cattle, nonlactating dairy cattle, and swine.

Regulatory Method for Residues

The analytical method for detection of residues of the drug is the cylinder plate microbiological test using Bacillus cereus var. mycoides (ATCC 11778) as outlined in the "Antibiotic Residues in Milk, Dairy Product and Animal Tissues: Methods, Reports, and Protocols" October 1968. National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

6. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, And Cosmetic Act satisfies the requirements of section 5123(n) of the Act and demonstrates that GEOMYCIN 200 (oxytetracycline hydrochloride) when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments:

The generic GEOMYCIN 200 (Oxytetracycline Injection) labeling and approved pioneer Liquamycin® LA-200® labeling.

Generic	Pioneer
100ml – bottle - Geomycin 200	100ml – bottle – Liquamycin LA-200
500ml – bottle - Geomycin 200	500ml – bottle – Liquamycin LA-200
Package insert - Geomycin 200	Package insert – Liquamycin LA-200