

JUL 21 1998

**FINDING OF NO SIGNIFICANT IMPACT
and
Environmental Assessment**

**Liquamycin LA-200
NADA 113-232 C0081**

**Pfizer
Animal Health Group
Exton, PA**

FOR PUBLIC DISPLAY

FDNS 1

FINDING OF NO SIGNIFICANT

**Liquamycin LA-200
NADA 113-232 C0081**

**Pfizer
Animal Health Group
Exton, PA**

The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment and that, therefore, an environmental impact statement will not be prepared.

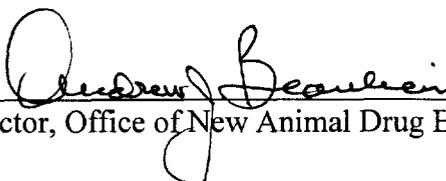
Pfizer is requesting approval of a supplement to the approved NADA for Liquamycin LA-200. The supplement provides for the addition of lactating dairy cattle to the existing labeling for Liquamycin LA-200. The indications, dosage and other conditions of use remain the same. Adding lactating dairy cattle to the label will not modify the introductions (concentration, temporal or spatial distribution) of oxytetracycline in the environment. Therefore, no changes in environmental exposures or effects are expected from the approval of the supplement.

In support of the supplement, the firm has requested a categorical exclusion from preparing an environmental assessment (EA) under old environmental regulations in 21 CFR 25.24. Under the old regulations, a categorical exclusion would not be appropriate because the addition of lactating dairy cattle to the label constitutes a new indication. A categorical exclusion under the new environmental regulations (62 FR 40596; 29 July 1997) in 21 CFR 25.33 is also not appropriate since the addition of lactating dairy cattle to the claim will result in an increase in the use of the drug. Therefore, an EA is necessary for the approval of the supplement.

The firm previously (7/14/89) submitted a supplement for the addition of lactating dairy cattle to the labeling for Liquamycin LA-200. At that time, the firm submitted an EA dated June 19, 1989, for the new claim and a FONSI was prepared. The supplement was subsequently denied. The EA submitted at that time remains appropriate for the current request. That EA contains information on the manufacturing of the product which is no longer required under the new regulation but in all other respects the EA adequately addresses the proposed use in lactating dairy cattle. Although the EA is old, the proposed use has not changed and the information in

the EA remains adequate to determine that the approval of the use of Liguamycin LA-200 in lactating dairy cattle will not have a significant effect on the human environment. A copy of the EA is attached.

4/25/98
Date



Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: June 19, 1989 Environmental Assessment and attachment

FINDING OF NO SIGNIFICANT IMPACT

for

Liquamycin® LA-200® (Oxytetracycline) Injectable
for Use in Cattle and Swine

NADA 113-232

Pfizer, Inc.
Lee's Summit, MO 64063

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement will not be required.

Pfizer, Inc., requested approval of a supplement to NADA 113-232 for the use of Liquamycin® LA-200® (oxytetracycline, 200 mg/ml) injectable in lactating dairy cattle to treat pneumonia and shipping fever complex associated with Pasteurella spp. and Hemophilus spp.; infectious bovine keratoconjunctivitis (pink eye) 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 Leptospira pomona; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. The drug is to be administered to cattle by intramuscular or intravenous injection at a level of 3 to 5 mg/lb BW/day. Treatment should be continued 24 to 48 hours following remission of disease signs, not to exceed a total of 4 consecutive days. However, a single dose of 9 mg/lb BW 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 re-treatment 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.

In support of the approval of this supplement to the NADA for Liquamycin® LA-200®, Pfizer provided the attached environmental assessment (EA) dated June 19, 1989. The EA indicates that the bulk drug will be manufactured by Pfizer facilities located in Groton, CN; Terre Haute, IN, or Sandwich England. The finished product is formulated and packaged at Pfizer's Lee's Summit, MO, plant. Pfizer certifies that the manufacturing facility complies with all applicable local, State and Federal environmental requirements. The additional use of oxytetracycline in lactating dairy cattle is expected to increase the use of oxytetracycline by less than 0.6% compared to that currently produced and sold for use in animals. No adverse environmental impacts are expected from the additional manufacture of this product. Therefore, the available information indicates that the use of oxytetracycline in the treatment of lactating dairy cows is not expected to have significant effects on the quality of the human environment.

10/16/89
Date

Wayne D. Alden
Preparer,
Environmental Sciences Staff, HFV-162

11/13/89
Date

Tom Jacobs
Primary Action Officer, HFV-133

10/16/89
Date

John C. Matheson
Chief,
Environmental Sciences Staff, HFV-162

Attachment: EA

cc: NADA 113-232 C048 B1
DUP
Division File (HFV-133)
HFV-100
HFV-162 (Reading/Office)
Wskidmore/HFV-162: 10/11/89
dlh 10/16/89 (P/F #45)



PFIZER INC.,

1107 SOUTH MISSOURI 291, LEE'S SUMMIT, MO 64063

(816) 524-5580

JUL 14 1989

Dr. Donald A. Gable, Director
Division of Therapeutic Drugs for Food Animals (HFV-130)
Center for Veterinary Medicine
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: NADA 113-232 - Liquamycin LA-200

Dear Dr. Gable:

Pfizer Inc. is submitting this supplemental New Animal Drug Application to provide for the use of Liquamycin LA-200 in treating diseases of lactating dairy cattle. Liquamycin LA-200 is currently approved for use in beef cattle and nonlactating dairy cattle. The approval of this application would expand the use of the product to treat lactating dairy cattle for the same disease conditions as currently approved.

In support of this application, Pfizer conducted a milk residue study in accordance with FDA's current "Guidelines For Establishing A Withdrawal Period" found in the Agency's "General Principles For Evaluating The Safety of Compounds Used In Food-Producing Animals." A copy of this study which supports an 84-hour milk withdrawal time is included in this submission. In addition copies of revised draft labeling, a Freedom of Information Summary and an Environmental Assessment are included for the Center's review.

The safety and efficacy of this product in cattle has already been established in NADA 113-232. This change has no effect on the manufacture of the product, therefore, there will be no change in the manufacture of Liquamycin LA-200 as currently approved in NADA 113-232.

Sincerely,

Perc W. Reeve, D.V.M.
Manager of Regulatory Affairs

PWR/jmm
(Attachment)

AGRICULTURAL DIVISION