FINDING OF NO SIGNIFICANT IMPACT
and
Environmental Assessment

Liquamycin LA-200
NADA 113-232 C0081

Pfizer
Animal Health Group
Exton, PA

FOR PUBLIC DISPLAY

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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 Liquamycin 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