

FINDING OF NO SIGNIFICANT IMPACT

for

Semduramicin Sodium Premix (AVIAX)

NADA 140-940

**Pfizer Inc.
New York, NY**

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 prepared.

Pfizer Inc. is requesting approval of their new animal drug application for the manufacture and use of AVIAX premix containing semduramicin sodium in broiler feed. The product would be fed continuously at 25.6 ppm for the prevention of coccidiosis.

In support of the new animal drug application, Pfizer has conducted a number of studies to determine the potential environmental fate and effects of semduramicin sodium and summarized the results of these studies in the attached environmental assessment (EA), dated April 5, 1993.

The EA evaluates the potential environmental impacts of the manufacture and use of the product. Precautions taken at the sites of manufacture of the bulk drug substance and the final product are expected to minimize occupational exposures and environmental release. These sites are stated to be in compliance with the applicable Federal, state and local environmental regulations. Therefore, the manufacture of the bulk drug and final product is not expected to have a significant impact on the environment.

To protect workers at the feed mixing site, cautionary statements about safe handling of the product are contained in the label on the premix. Also, Pfizer provides material safety data sheets to its feed mill customers.

Information in the EA demonstrates that most of the ingested drug is broken down by the broiler into many polar metabolites. Combining the concentrations of parent drug and the one biologically active metabolite results in an estimated concentration of 3.7 ppm biologically active residues in excreta. Residues of semduramicin are expected to be introduced into soil through the application of excreta and litter from broilers as fertilizer. These residues are expected to be moderately bound to and biodegraded in the soil. Pfizer has calculated that the maximum possible concentration of semduramicin (assuming no degradation of drug during storage of the litter) expected in agricultural soils following the application of fresh broiler litter from broilers fed feed containing AVIAX premix could be 0.03 ppm. Over time, the concentration of the drug is expected to decrease because it is biodegraded in soil.

Analysis of data from two definitive plant studies indicates that residues of semduramicin in agricultural soil are not expected to have adverse impacts on plants.

Minimum inhibitory concentration (MIC) tests of soil microorganisms demonstrate that the residues are not expected to have adverse impacts on soil microorganisms.

The EA estimates that runoff from these soils would contain a maximum potential concentration of 0.14 ppm (this estimate assumes no biodegradation or soil sorption). CVM used a more conservative means of calculation of the concentration and arrived at an estimate of 0.24 ppm. This difference in estimated values would not change the conclusions of the EA. Actual runoff concentrations would be expected to be less than either of the estimates. Data in the EA indicate that semduramicin is moderately sorbed to three different soil types. Soil sorption reduces the likelihood that a chemical will be found in runoff water, groundwater, or the atmosphere.

Projected concentrations in runoff water are considerably less than the LC50's for rainbow trout, bluegill, *Daphnia magna*, and the freshwater alga *Selenastrum capricornutum*. Therefore, the use of the drug is not expected to have significant impacts on aquatic species.

6/17/93
Date

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6/18/93
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Attachment: Environmental Assessment, dated April 5, 1993