

FINDING OF NO SIGNIFICANT IMPACT

FOR

Apralan[®] (Apramycin Sulfate) Soluble Powder
for Colibacillosis in Weanling Pigs

Elanco Products Company, a Division of Eli Lilly and Company, has filed and received approval for a new animal drug application (NADA 106-964) to market a water soluble powder of apramycin sulfate to treat weanling pigs for colibacillosis. The drug will be administered in drinking water for seven days at a concentration of 0.75 grams apramycin activity/gallon of drinking water. Colibacillosis is a frequent intestinal disorder of pigs at weaning. Administration of drugs through drinking water at weaning time is a more effective means of dosing than use of medicated feed, since pigs eat very little feed at this life stage.

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

The evidence supporting the Bureau's finding is contained in the attached environmental impact analysis report and summary of environmental studies prepared by the drug sponsor and reviewed and further summarized in the attached Environmental Impact Data Sheet by Bureau environmental scientists. Apramycin degrades slowly (half-life greater than 1 year) but is strongly adsorbed to soil particles and is therefore relatively unavailable to soil microorganisms and invertebrates. At the levels at which apramycin residues would be expected to enter and accumulate in agricultural soils (as a result of using swine wastes in fertilizer), no adverse environmental effects on soil or aquatic organisms are anticipated. Also, no adverse effects are expected from the relatively higher concentrations of apramycin residues that would be expected to enter swine waste stabilization systems.

12/22/81
Date

Gilbert Samuelsen
Primary Action Officer (HFV-138)

12/18/81
Date

John C. Mathews
Preparer and Chief
Environmental Impact Staff (HFV-310)
Bureau of Veterinary Medicine

Attachments