

FINDING OF NO SIGNIFICANT IMPACT

for

Apralan® Premix for Swine

NADA 126-050 C018

Elanco Products Company

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 and that an environmental impact statement therefore will not be prepared.

Elanco Products Company is requesting approval of Apralan® (apramycin) premix to be used in the feed of swine for the treatment of porcine colibacillosis. About 150 grams of apramycin activity as sulfate salt would be added to each ton of feed and used for a maximum of 14 days in the feed of young swine.

Elanco submitted an environmental assessment on August 1, 1985. The assessment adequately addresses the potential environmental impacts of the manufacture and use of the product that would be marketed as a result of the new animal drug approval, as required by 21 CFR 25.31a(a) (50 FR 16636, April 26, 1985, effective July 25, 1985).

11/19/85
Date

Gilbert Samulson DVM
Primary Action Officer, HFV-~~128~~
133

9/23/85
Date

J C Matheson M
Preparer and Chief, Environmental Staff, HFV-152

cc: Orig. & Dup., (NADA 126-050 C018) ✓
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JCMatheson:cbm:9/20/85