FINDING OF NO SIGNIFICANT IMPACT

for

Efrotomycin for Swine

NADA 140-818

MSD AGVET
A Division of Merck & Co., Inc.

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.

MSD AGVET, a division of Merck & Co., is requesting approval of Producil® (efrotomycin) to be included in the feed of swine from weaning to slaughter at concentrations varying from 1.8 to 14.5 grams/ton for increased rate of weight gain and improved feed efficiency.

In support of their new animal drug application, the firm has submitted an environmental assessment (EA) and associated environmental studies. We have reviewed the EA and each of the studies and find that they are adequate to predict that the proposed use of efrotomycin will not result in adverse environmental effects.

Efrotomycin residues are fairly rapidly degraded in the presence of sunlight and without sunlight at normal soil pH ranges. The residues bind moderately to most soils. Toxicity studies with microbial communities, aquatic crustaceans and fish, earthworms, algae and plants indicate that adverse effects from efrotomycin residues at the highest expected concentrations are not anticipated.

This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25) that was published in the FEDERAL REGISTER of April 26, 1985 (50 FR 16636, effective July 25, 1985).

10-14-86
Date

Primary Action Officer, HFV-128

10-10-86
Date

Preparer and Chief
Environmental Staff, HFV-152

Attachment

FINDING OF NO SIGNIFICANT IMPACT

for

JUL 24 1992

Efrotomycin For Swine

NADA 140-818

Merck Sharp & Dohme Research Laboratories
Rahway, New Jersey

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.

Merck Sharp & Dohme Research Laboratories submitted an amendment (dated June 23, 1986) to NADA 140-818 that provides for the alternative manufacturing of efrotomycin at Merck's Haarlem, Holland. A second amendment (dated December 9, 1991) to the NADA 140-818 was submitted by Merck requesting deletion of 1.8 grams efrotomycin/ton of the feed from the previously requested concentrations (1.8 to 14.5 grams/ton).

The information provided in the supplement for the Merck's Haarlem, Holland manufacturing facility is adequate to determine that the manufacture of efrotomycin at this site is not expected to have a significant impact (including occupational) on the environment. A copy of the amendment is attached to environmental assessment (EA). Additionally, Merck has a recent approval (see FR notice dated December 7, 1990) to use this facility and the Danville, Pennsylvania, facility for the manufacture of ivermectin Pour-On. Therefore, there is sufficient information to reaffirm that the manufacture of efrotomycin at the Haarlem and Danville manufacturing facilities will not have a significant impact (including occupational) on the environment.

The amendment requesting the deletion of 1.8 grams efrotomycin/ton of the feed from the previously requested concentrations (1.8 to 14.5 grams/ton) is adequately covered in the firm's 1986 EA and does not alter the conclusions expressed in that EA (dated 23 June 1986) and FONSI (dated October 10, 1986).

We have reviewed the amendments and have determined that the requested amendments are not expected to have a significant impact on the human environment and there is no reason to expect that this alters the conclusions expressed in the attached EA and October 10, 1986, FONSI covering the approval of this NADA.

7/9/92
Date

Primary Action Officer, HFV-128