

FINDING OF NO SIGNIFICANT IMPACT

for

Denagard® (tiamulin) Premix

NADA 139-472 R003

Fermental Animal Health 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.

Fermenta has submitted a supplemental new animal drug application requesting approval of an expanded use of tiamulin in the feed of swine. The application would extend the use of tiamulin in feed at the concentration of 10 grams per ton to swine weighing from 125 pounds to market weight for increased rate of weight gain and improved feed efficiency. The product is previously approved for these purposes and at this concentration for swine from weaning to 125 pounds.

The firm, previously known as SDS Biotech, had earlier requested these uses to be approved and had submitted an environmental assessment which addressed the extended use currently being requested. The firm, however, has submitted a revised environmental assessment, dated July 11, 1988, to support the new supplemental application. We have reviewed this revised environmental assessment and find that it adequately addresses the potential environmental impact of the new use. The product is manufactured with adequate controls to prevent occupational and other environmental problems. Very little of the product can enter the environment as a result of the use of the product; it is extensively metabolized by swine.

7-18-88

Date

Gilbert Samuelson

Primary Action Officer, HFV-133

7-15-88

Date

J. C. Matheson III

Preparer and Chief,
Environmental Sciences Staff, HFV-162

Attachment: Environmental Assessment, July 11, 1988