FINDING OF NO SIGNIFICANT IMPACT

for

Denagard® (tiamulin) Medicated Premix
For Use in Swine

NADA 139-472 S0048

Fermenta Animal Health
Elwood, KS

FOR PUBLIC DISPLAY

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Fermenta Animal Health
Elwood, KS

The Center for Veterinary Medicine has carefully considered the potential environmental effects of this action and has concluded that this action will not have a significant impact on the quality of the human environment. Therefore, an environmental impact statement will not be required.

Fermenta Animal Health Company is requesting the approval of a supplement to new animal drug application (NADA) 139-472 for Denagard® (tiamulin) medicated premix for the treatment of swine dysentery due to *Treponema hyodysenteriae*. The therapeutic regimen is for 200 g tiamulin hydrogen fumarate/ton of swine feed for 14 days. Tiamulin is currently approved for the control of swine dysentery associated with *Treponema hyodysenteriae* at a dose of 35 g tiamulin/ton swine feed for continuous use under 21 CFR 558.600.

Fermenta Animal Health, has submitted the attached abbreviated environmental assessment (EA; signed January 11, 1994). The bulk tiamulin hydrogen fumarate will be manufactured by a foreign manufacturer and the finished product will be manufactured by Fermenta Animal Health Company, Elwood, KS.

For the sites of manufacture, the EA identifies the chemical substances that are expected to be emitted in to the environment, cites applicable Federal, State, and local emission requirements, and provides 1) permit number for the installation and operation of exhaust system issued by the Bureau of Air and Waste Management, Kansas Department of Health and Environment, Topeka, KS; 2) Environmental Protection Agency (EPA) Hazardous Waste Generator Identification Number; and 3) Water Pollution Control Permit Number. The EA states that personnel who handle the drug product are protected from potential inhalation and dermal hazards by requiring that they wear a dust respirator and protective gloves along with a complete work uniform, safety glasses, and safety shoes. The EA contains a certificate of compliance with the applicable Federal, State, and local emissions requirements. A material safety data sheet (MSDS) for Denagard® (tiamulin) medicated premix is provided as an attachment to the EA.

The EA also discusses the fate of the emitted substances in the environment. The EA states that tiamulin is extensively metabolized in swine and more than 25 metabolites have been synthesized and tested for antibacterial activity. Most of the metabolites have little or no antibacterial activity.

The firm refers to a Veterinary Master File (VMF) for the environmental and occupational safety information for the manufacture of bulk tiamulin hydrogen fumarate. The EA submitted to the VMF contains adequate environmental and occupational safety information for the manufacture of bulk tiamulin hydrogen fumarate.

We have reviewed the EA for the finished product manufacturing facility and the MSDS for Denagard® (tiamulin) medicated premix and the EA in VMF for bulk tiamulin hydrogen fumarate and have determined that they are adequate to show that the action is not expected to have a significant impact on the human environment.

4/6/94
Date

D.N. Jayanna
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4/6/94
Date

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4/6/94
Date

Robert C. Livingston
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Attachments: EA; signed January 11, 1994