FINDING OF NO SIGNIFICANT IMPACT

for

Porcilene®
(fenprostalene)
Sterile Solution
for Swine

SYNTEX
Palo Alto, CA

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.

On May 25, 1988, SYNTEX submitted the attached environmental assessment (EA) in support of a new animal drug application (NADA 138-903) for the use of Porcilene® (fenprostalene) Sterile Solution in swine for the induction of parturition. The product will be administered as a single subcutaneous injection of 0.25 mg to sows and gilts that have been pregnant at least 112 days.

We have reviewed the EA and find it adequate. The EA provides information indicating that the product will be manufactured in Des Moines, Iowa, and Cuernavaca, Mexico. The manufacture of the product is not expected to cause significant environmental effects and employees are expected to be adequately protected. Information in the EA also indicates that only a small amount of the product is expected to be introduced into the environment and that it is not expected to have a significant impact.

8/3//88 Date

Preparer,

Environmental Sciences Staff, HFV-162

<u>8/3//8</u>8
Date

Primary Action Officer, HFV-126

8/31/88

Ch**i**ef,

Environmental Sciences Staff, HFV-162

Attachment