

FINDING OF NO SIGNIFICANT IMPACT

for

**Morantel Tartrate (RUMATEL 88®)
Type A Medicated Article
for Use in Goats**

NADA 092-444

**PFIZER, INC.
LEE'S SUMMIT, MO**

FOR PUBLIC DISPLAY

MAR 17 1994

FINDING OF NO SIGNIFICANT IMPACT

Rumatel 88
(morantel tartrate)
for Use in Goats
NADA 92-444 R059

Pfizer Animal Health
Lee's Summit, MO

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.

Pfizer Animal Health is requesting approval of a supplement to its new animal drug application (NADA) 92-444 for Rumatel 88 medicated article to include the use of morantel tartrate for the removal and control of mature gastrointestinal nematode infections in goats. The product is to be used at a dose of up to 4.4 grams of morantel tartrate per pound of body weight.

In support of the supplement, the firm provided the attached environmental assessment (EA) dated July 20, 1993, for the final manufacturing (blending and packaging) of the product for the proposed new use. The EA provides a list of emissions expected from the manufacturing, describes the emissions controls at the facility, and cites, and certifies that the facility is in compliance with the applicable environmental requirements. The EA does not discuss bulk manufacturing and during a December 21, 1993, telephone conversation between Mr. Charles Eirkson of The Center for Veterinary Medicine and Dr. John Horigan of Pfizer, it was confirmed that the bulk manufacturing would be at the same facility and under the same conditions as already approved in the NADA. With this clarification, the EA is adequate to determine that the manufacture of the product (Rumatel 88) is not expected to have a significant impact on the environment.

The firm also references the March 1991, EA that addresses the use of the product in goats. The EA was prepared by Dr. Stanley Katz for the Interregional-Research project. A copy of the EA is attached. Although this EA was prepared for the use of the product in lactating dairy goats, the information and conclusions in the EA are applicable to all goats. The EA concluded that there does not appear to be any potential for disruption of the environment from the proposed use of morantel tartrate and that the molecule is expected to be biologically and photolytically degraded. Therefore, the EA is adequate to conclude that the use of Rumatel 88 in goats is not expected to have a significant impact on the environment.

12/27/93
Date

Amulligan

Director
Division of Toxicology and Environmental Sciences
HFV-150

12/27/93
Date

Charles E. Ecker

Preparer and Chief,
Environmental Sciences Staff
HFV-152

12-29-93
Date

Melanie W. Benson, DVM

Primary Action Officer, HFV-135

Attachment: Environmental Assessments, dated July 20, 1993, and March 1991