

FINDING OF NO SIGNIFICANT IMPACT

for

RALGRO® MAGNUM (Zeranol 72 mg implants)
for Feedlot Steers

NADA 038-233 R0075

Mallinckrodt Veterinary, Inc.
Mundelein, IL

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 prepared.

Ralgro® Magnum 72 mg is an ear implant (containing six 12 mg zeranol pellets) is a slow release anabolic product that provides for increase rate of weight gain in feedlot steers.

This NADA provides for the use of zeranol at a higher dosage level than the 36 mg product previously approved under 21 CFR §522.2680. The duration and indications of use are the same as those previously approved. Mallinckrodt Veterinary, Inc., has prepared and submitted the attached environmental assessment (EA, dated August 1994) under 21 CFR 25.31a(a) for the manufacture and use of zeranol for this action. The active ingredient and the finished product are manufactured at the Mallinckrodt Veterinary, Inc., facility in Terra Haute, IN.

For the sites of manufacture, information in the EA 1) identifies the substances expected to be emitted, 2) states that appropriate controls as required by the Federal, State and local emissions requirements, are used in all phases of manufacture, and 3) provides air operating permit numbers. For the disposal of wastewater, the EA provides the National Pollutant Discharge Elimination System (NPDES), and Terra Haute Wastewater Treatment Plant permit numbers. Because zeranol has low estrogenic activity in mammalian species, the EA identifies precautions that are to be taken to protect employees from exposure to the active drug substance during the manufacture of the product and indicates that adverse occupational effects are not anticipated. The EA includes statements of compliance with applicable emissions requirements and discusses the effect the approval this supplement will have upon compliance with the current emissions requirements.

The new introduction of the drug into the environment from use of the product on feedlot steers has also been considered in the EA. The EA states that concentration of zeranol in the soil due to the practice of using manure as fertilizer would be approximately 1.0 ppt, and introduction from field run-off would be 400 ppt. Any introduction of the product into the environment from the use is not expected to have a significant effect on the environment because zeranol is readily and extensively mineralized to CO₂. The EA therefore, supports a conclusion that the use and manufacture of the product is not expected to have a significant impact on the environment.

We have reviewed the EA including the supporting information and have determined that the manufacture and proposed deletion of the labeling disclaimer against the use of 72 mg zeranol in feedlot steers is not expected to have a significant impact on the human environment.

11/22/94
Date

Dr. Jayaramath
Reviewer, Environmental Sciences Staff, HFV-152

11/22/94
Date

Edison L. Monk
Primary Action Officer, HFV-126

11/22/94
Date

Charles E. Goshaw
Chief, Environmental Sciences Staff, HFV-152

Attachment: Environmental Assessment, dated August 1994