

FINDING OF NO SIGNIFICANT IMPACT

for

Revalor[®]-H
(Trenbolone Acetate + Estradiol Implants)

Hoechst-Roussel Agri-Vet
Somerville, NJ

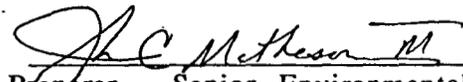
The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Hoechst-Roussel Agri-Vet is proposing the combination of trenbolone acetate (140 mg) and estradiol (14 mg) in implants to be used in feedlot heifers. Implant pellets would be prepared that individually contain 20 mg trenbolone acetate and 2 mg estradiol. Multiple pellets would be implanted into the ear of each feedlot heifer once only.

Use of trenbolone acetate in heifers at up to 200 mg per head is already approved under 21 CFR 522.2476. Estradiol implants containing up to 24 mg are approved at 21 CFR 522.840 for heifers. The proposed dosage is below those already approved for separate administration to heifers. However, new manufacturing sites are to be used to produce this product. Consequently, an abbreviated Environmental Assessment has been provided by the sponsor that addresses only the manufacture of the trenbolone acetate and estradiol bulk drugs and the finished trenbolone + estradiol implants.

The environmental information provided by Hoechst is sufficient for CVM to determine that the manufacture of this product is not expected to have a significant impact on the environment.

7/12/94
Date


Preparer, Senior Environmental Scientist, HFV-150

7/19/94
Date


Primary Action Officer, HFV-126

7/12/94
Date


Chief, Environmental Sciences Staff, HFV-152

Attachment: Environmental Assessment, dated March 1994