FINDING OF NO SIGNIFICANT IMPACT

for

NADA 140-897 Revalor®-G (Estradiol + Trenbolone) for Steers on Pasture

> Hoechst-Roussel Agri-Vet Somerville, NJ

FINDING OF NO SIGNIFICANT IMPACT

for

NADA 140-897 Revalor®-G (Estradiol + Trenbolone) for Heifers on Pasture

> 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 use of a subcutaneous implant containing trenbolone acetate and estradiol benzoate for heifers on pasture. One Revalor[®]-G dose contains a total of 40 mg of trenbolone acetate and 8 mg of estradiol. The implant is administered as two small yellow pellets in one ear of each heifer. The product is indicated for increased rate of weight gain.

Essentially all feedlot heifers are currently implanted with growth-promoting drugs, including products containing trenbolone acetate and estradiol, at the beginning of the feeding period. The effect of the proposed new use will be to allow a much lower dose of trenbolone to be used in heifers held in pastures. Revalor[®]-G has been previously approved at the proposed doses for use in pastured steers.

In support of their application, Hoechst-Roussel Agri-Vet has provided an environmental assessment, dated April 1, 1996 that addresses the manufacture of the implant ingredients and the potential environmental impact of the additional use of trenbolone in the heifer population. The incremental additional use proposed in this application is not expected to change significantly the nature of the residues or their concentrations in the environment.

Date

Director, Office of New Animal Drug Evaluation, HFV-100

Attachment: Environmental Assessment, dated April 1, 1996