

FINDING OF NO SIGNIFICANT IMPACT

for

NADA 141-043 E0006
Synovex[®] Plus (Estradiol + Trenbolone)
for Steers in Confinement

Syntex Agribusiness
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

Syntex is proposing the use of a subcutaneous implant containing trenbolone acetate and estradiol benzoate in steers fed in confinement for slaughter. One Synovex[®] Plus dose contains a total of 200 mg of trenbolone acetate and 28 mg of estradiol benzoate. The implant is administered as eight pellets in one ear to improve feed efficiency. Essentially all feedlot steers are currently implanted with growth-promoting drugs at the beginning of the feeding period. The effect of the proposed new use will be to allow an increase in the trenbolone content in such implants from 120 mg to 200 mg per head. 200 mg is the dose already approved for feedlot heifers. Estradiol benzoate at 28 mg has been previously approved for steers.

In support of their application, Syntex has provided an environmental assessment, dated November, 1995, that addresses the manufacture of the implant ingredients and the potential environmental impact of the additional use of trenbolone in the steer population. Although there remain uncertainties as to the overall impacts of trenbolone residues in the environment, resulting from all uses in cattle, the incremental use proposed in this application is not expected to change significantly the nature of the residues or their concentrations in the environment.

1-4-96
Date


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

Attachment: Environmental Assessment, dated November 1995