

FINDING OF NO SIGNIFICANT IMPACT

for

REVALOR®-S (trenbolone acetate +
estradiol) Ear Implant for Feedlot Steers

(NADA 140-897)

Hoechst-Roussel Agri-Vet Co.
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. Therefore, an environmental impact statement will not be required.

REVALOR®-S (trenbolone acetate + estradiol) is an ear implant containing 140 mg trenbolone acetate and 28 mg estradiol in a combination product which is a slow release anabolic agent that increases weight gain and improves feed efficiency in feedlot steers.

This NADA provides for the use of estradiol at a lower dosage level than that previously approved under 21 CFR 522.840 and trenbolone acetate at the same dosage level as that previously approved under 21 CFR 522.2476. The duration and indications of use are also the same as those previously approved. Therefore, the product could qualify for a categorical exclusion under 21 CFR 25.24(d)(1)(ii) from the requirements to prepare an environmental assessment (EA). However, Hoechst-Roussel Agri-Vet Company has prepared and submitted an EA (copy attached) for this combination product. The EA provides information applicable under 21 CFR 25.31(a)(b)(5) for the naturally occurring estradiol component of the product. The EA also contains reference to the previous EA dated April 1987 which provided for the approval of trenbolone acetate (NADA 138-612).

For the sites of manufacture, information in the EA identifies the pollutants expected to be emitted, states the methods to control air, water and solid emissions, includes a statement of compliance with applicable emissions requirements and discusses the effect the approval of this NADA will have upon compliance with the current emissions requirements. The EA also identifies precautions that are taken to protect employees from exposure to the active drug substances during the manufacture of the product and indicates that adverse occupational effects are not anticipated. The EA therefore, supports a conclusion that the manufacture of the product is not expected to cause significant environmental impacts.

7/1/88
Date

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Preparer,
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7/6/88
Date

Jack C. Taylor
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7/1/88
Date

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Attachment