

FINDING OF NO SIGNIFICANT IMPACT

for

Implus-C ® (progesterone and estradiol benzoate) Implants for Calves

NADA 110-315

Ivy Laboratories, Inc.
Overland Park, KS

The Center for Veterinary Medicine has 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, therefore, an environmental impact statement will not be prepared.

Ivy Laboratories Inc., has requested approval of a supplement to NADA 110-315 that provides for the use of progesterone and estradiol benzoate (Implus-C ®) implants for increased rate of gain in suckling heifer calves intended for reproductive purposes. The product is currently approved for increased rate of weight gain in suckling beef calves up to approximately 400 lbs of body weight. In support of the approval, Ivy Laboratories Inc., has provided information in a environmental assessment (EA) dated November 7, 1996.

The EA provides information concerning environmental introductions resulting from the manufacture and use of the product. The bulk drug substance and finished drug product will be manufactured at the sponsor's facility in Overland Park, KS. Certifications that the sites are in compliance with applicable environmental requirements are provided. The EA states that occupational safety information and safe product handling policies for workers are in place.

The EA provides information on the substances expected to enter the environment, fate, and the environmental effects as a result of the use of the product.

We have reviewed the EA and find that it is adequate to conclude that the manufacture and use of Implus-C ® (progesterone and estradiol benzoate) implants for increased rate of gain in suckling heifer calves intended for reproductive purposes is not expected to have a significant impact on the environment.

12-5-96
Date

R. C. Livingston
Director, Office of New Animal Drug Evaluation, HFV-100