

MAY - 2 2002

FINDING OF NO SIGNIFICANT IMPACT

for

CIDR Intravaginal Progesterone Inserts

DEC International
Madison, Wisconsin

For Public Display
(HFA-305)

NADA 141-200

FNSI

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for

CIDR Intravaginal Progesterone Inserts

DEC International
Madison, Wisconsin

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 impact on the quality of the human environment and therefore an environmental impact statement will not be prepared.

DEC International has submitted a new animal drug application (NADA) for the approval of CIDR Progesterone Intravaginal Inserts for estrus synchronization in beef cows and in beef and dairy heifers. In support of the application, the drug sponsor has submitted an Environmental Assessment.

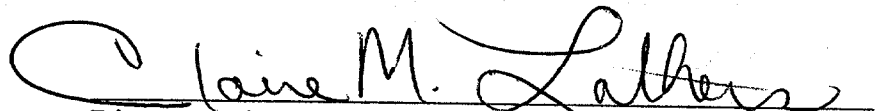
The EA provides information on the contribution of progesterone from the inserts as compared to total excreted progesterone from cattle. The EA provides adequate information on the use of the inserts, a conceptual model of exposed ecosystems, environmental fate data and estimates of environmental concentrations. A risk characterization, based on the items listed below, indicates that the use of intravaginal progesterone inserts to synchronize estrus in beef cows and beef and dairy heifers is not expected to negatively impact the environment.

- Progesterone is a naturally occurring substance. The amount of progesterone excreted into the environment from cows treated with the insert is less than 1% of that excreted by non-treated cows on an annual basis. The amount of insert progesterone excreted by the target species is negligible compared to all natural sources of progesterone that enter the environment.
- Progesterone is metabolized to more polar compounds in beef cows and heifers. Therefore, excretion of progesterone into the environment will be less than 100% of the absorbed amount during the 7-day treatment period.
- Concentrations of progesterone in the environment from use of the intravaginal progesterone insert are predicted to be extremely low (≤ 1 ng/kg in soils).

- Based on conclusions reached for related compounds, progesterone is likely to be biodegraded in soils to more polar metabolites and carbon dioxide. Several microbial species in the environment can use progesterone as a source of carbon and energy.
- Progesterone is not expected to be mobile in soils. Parent progesterone and/or progesterone-like residues should bind extensively to soil matrices and, therefore, become less bioavailable to non-target species.

We have reviewed the EA and find that it is adequate to determine that significant environmental impacts are not expected from the approval of the NADA for this product.

1/31/02
Date


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

Attachment: Environmental Assessment, dated November 16, 2001