

FINDING OF NO SIGNIFICANT IMPACT

for

IVOMEC Pour-On for Cattle

Merial Limited
3239 Satellite Blvd
Duluth, GA 30096

For Public Display
(HFA-305)

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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.

Merial Limited has submitted a supplement to new animal drug application (NADA) 140-841: IVOMEC Pour-On for the treatment and control of internal and external parasites in feedlot and pasture cattle. The product is to be applied at 0.5mg ivermectin/kg body weight applied topically using an appropriate dosing device. The supplement to the NADA was submitted to add persistence activity claims to the existing indications. In support of the application, the drug sponsor has submitted an updated Environmental Assessment (EA; dated May 2, 2001).

The EA provides environmental fate and effects data from the original avermectin-based cattle product EAs and summarizes and assesses subsequent literature and information. Key dung fauna and dung degradation literature from 1993-2000 is reviewed in detail. The updated EA responds to Agency concerns about potential effects of avermectin residues on insect populations in dung, effects on higher trophic levels, and chronic effects on soil organisms.

As discussed in the EA, the avermectins are recognized to be highly toxic to a variety of insects that use cattle dung for growth and reproduction. In order to allow users to make informed decisions about the use of such products, the following Environmental Safety statement is to be included on package inserts for avermectin-based cattle products:

As with other avermectins, [the active ingredient of this product] is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

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

11-15-02

Date

Steven D. Vaughn DVM

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

Attachment: May 02, 2001, Environmental Assessment