FINDING OF NO SIGNIFICANT IMPACT

for

Eprinomectin Extended-Release Injectable Parasiticide for Cattle

Merial Limited
3239 Satellite Blvd
Duluth, GA 30096

For Public Display

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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 new animal drug application (NADA) for Eprinomectin Extended-Release Injectable Parasiticide for Cattle (ER) for the treatment and control of various internal and external parasites in pastured cattle. Each mL of Eprinomectin ER contains 50 mg eprinomectin. The product is administered subcutaneously to non-lactating cattle at a dose rate of 1 mg eprinomectin per kilogram bodyweight. The product will not be labeled for use in cattle managed in feedlots or under intensive rotational grazing. In support of the application, the drug sponsor has submitted an Environmental Assessment (EA; dated September 20, 2010) that assesses the potential effects on the environment due to use of the product.

The submitted EA considers impacts on terrestrial organisms; aquatic and benthic organisms, dung fauna, and potential effects on dung degradation rates. With respect to insecticidal effects, eprinomectin residues in individual dung pats may disrupt insect development; however, based on drug use patterns, no significant impact on dung-dependent insect populations is expected. No significant impacts on higher trophic levels that feed on dung insects are anticipated.

In order to allow users to make informed decisions about the use of Eprinomectin ER, the following statements are to be included on package inserts for this product:

As with other avermectins, eprinomectin 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.

Environmental Safety: Studies indicate that when eprinomectin comes in contact with soil, it readily and tightly binds to the soil and becomes inactive over time. Free eprinomectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Not for use in cattle managed in feedlots or under intensive rotational grazing because the environmental impact has not been evaluated for these scenarios.

The following language will be placed on container and carton labels:

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Not for use in cattle managed in feedlots or under intensive rotational grazing.

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 NADA.

10-01-2010
Date

Steve D. Vaughn DVM
Director, Office of New Animal Drug Evaluation, HFV-100

Attachment: September 20, 2010, Environmental Assessment