

NOV 2 1999

FINDING OF NO SIGNIFICANT IMPACT

and

Environmental Assessment

for

**CYDECTIN[®] (moxidectin)
Pour-on for Cattle**

**Fort Dodge Animal Health
Princeton, NJ**

For Public Display
Food and Drug Administration
Docket Management Branch
HFA-305

NAD 141-099

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

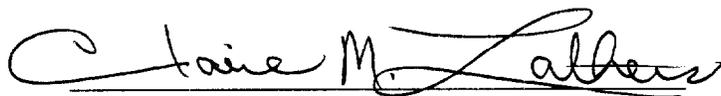
Fort Dodge Animal Health is requesting approval of a supplemental new animal drug application (NADA) for CYDECTIN[®] (moxidectin) Pour-on for lactating dairy cattle. The NADA provides for the use of 0.5% moxidectin in a single topical application for the treatment of infestations of specified internal and external parasites. CYDECTIN[®] is currently approved for use in non-lactating dairy and beef cattle. The current approval will expand the use to include lactating dairy cattle.

In support of the NADA, Fort Dodge has provided the attached August 24, 1999, environmental assessment (EA). The information provided in the EA predominantly references the information submitted in the June 12, 1997, environmental assessment (EA) for the approval of the NADA for the use of CYDECTIN[®] in non-lactating dairy and beef cattle. The information provided in the EA indicates that the environmental fate of moxidectin is expected to be comparable to other already approved avermectin products, such as ivermectin, eprinomectin, and doramectin. All avermectins have very low water solubility, high octanol/water partition coefficient, extremely high binding to soils and sediment. They all have similar environmental effect characteristics. That is, the data indicate that they are extremely toxic to invertebrate crustaceans and insects, toxic to aquatic vertebrates, and relatively nontoxic to birds, plants and annelids (earthworms), as determined through tests on indicator species.

There are concerns for impacts on aquatic organisms but they are reduced because moxidectin binds to soil and sediment. This limits the concentration of free moxidectin in surface water. To assure that free moxidectin does not enter surface water, an environmental safety warning and direction are included on the label of the product. There is also concern for toxicity to dung dependent insects but data in this and other avermectin EAs indicates that the approved use (indications, dosage and duration of use) for the product will limit the avermectins' spatial and temporal distribution. Therefore, they are not expected to have a significant effect on populations of dung dependent insects.

Based upon the information provided in the EA, including the information to indicate that moxidectin behaves substantially the same as other avermectins that have the same indications and similar dosages, the use of CYDECTIN[®] (moxidectin 0.5%) Pour-on for lactating dairy cattle is not expected to have significant impact on the human environment.

8/30/99
Date


Director, Office of New Drug Evaluation, HFV-100

Attachment: August 24, 1999, Environmental Assessment