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

FINDING OF NO SIGNIFICANT IMPACT

for

CYDECTIN® (moxidectin)
Pour-on for Cattle

Fort Dodge Animal Health
Princeton, NJ

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 new animal drug application (NADA) for CYDECTIN® (moxidectin) Pour-on for 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.

In support of the NADA, Fort Dodge has provided the attached June 12, 1997, environmental assessment (EA). 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 soil and sediment. They all have similar environmental effect characteristics. That is, the data indicate that they are extremely toxic to invertebrates (crustacean and insect), toxic to aquatic vertebrates, and relatively nontoxic to birds, plants and anal ids (earthworms), as determined through tests on indicator species. Concerns for impacts on aquatic organisms are reduced because of binding to soil and sediment, which limits the concentration in water. Toxicity to dung dependent insects is also a concern for the avermectin products, but data in this and other avermectin EAs indicate that because of the avermectins' spatial and temporal distribution, they are not expected to have a significant effect on populations of dung dependent insects. Additionally, there are data in the attached EA to indicate that moxidectin is relatively less toxic to invertebrates than other avermectins.

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 cattle is not expected to have significant impact on the human environment.

12-23-97
Date

Director Office of New Drug Evaluation, HFV-100

Attachment: June 12, 1997, Environmental Assessment