

FINDING OF NO SIGNIFICANT IMPACT

for

RUMENSIN® (Monensin) for Use in Cattle

NADA 95-735 R005

Elanco Products Company
Indianapolis, IN 46285

The Center for Veterinary Medicine has carefully 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. Therefore, an environmental impact statement will not be required.

Elanco Products Company has submitted a supplemental new animal drug application (NADA 95-735, R005) for the use of monensin (RUMENSIN®) in feed for the control of coccidiosis in feedlot cattle. The monensin feeding levels (10 to 30 g/ton, or 100 to 360 mg monensin/head/day) for the proposed claim are within the range of those previously approved for improved feed efficiency [21 CFR 558.355(f)(3)].

In support of the approval of the NADA for the product, Elanco Products Company submitted an attached environmental assessment (EA dated August, 1989) under 21 CFR 25.31a(a) that addresses the potential environmental impacts of the increase in the manufacture and use of monensin to control coccidiosis in feedlot cattle. The EA indicates that the increase in manufacture and use of monensin for the control of coccidiosis will amount to less than 1% of the monensin already sold and used in the U.S. Some precautions are necessary for workers when handling the concentrated bulk drug and premix. The potential for any adverse effects on workers handling these materials is adequately mitigated by the inclusion on the premix label of instructions for the safe handling of these materials and for steps to take in the event of an accidental exposure.

We have reviewed the EA and determined that the proposed action to use monensin to control coccidiosis in feedlot cattle is not expected to have a significant impact on the human environment.

12/6/89
Date

Wesley D. Sidman
Preparer,
Environmental Sciences Staff, HFV-162

12.06.1989
Date

J. L. Fitts
Primary Action Officer, HFV-135

12/6/89
Date

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Attachment: EA