

FINDING OF NO SIGNIFICANT IMPACT

for

Monensin (Coban 45) for Turkeys

NADA 130-736

Elanco Products Company

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 and that an environmental impact statement therefore will not be prepared.

Elanco Products Company has submitted a new animal drug application that would provide for the use of monensin in the feed of turkeys for the prevention of coccidiosis. The medicated feed would contain monensin activity (as monensin sodium) equal to 54 to 90 grams per ton (60 to 100 ppm) and would be provided to growing turkeys from day 1 to 10 weeks of age. The same product is previously approved at a higher dose range as an aid in the prevention of coccidiosis in broiler chickens.

In support of their new animal drug application, the firm has prepared an environmental assessment (attached) addressing the potential for the proposed manufacture and use of monensin in turkeys to cause environmental impacts. Some precautions are necessary to protect workers 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 steps to take in the event of an accidental exposure.

The Center has reviewed the environmental assessment prepared by the firm, the supporting environmental studies submitted as part of this application and other environmental information submitted in support of the use of monensin in chickens and cattle. We find that the proposed use of monensin in turkeys is not expected to cause significant environmental effects.

This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25) that was published in the FEDERAL REGISTER of April 26, 1985 (50 FR 16636, effective July 25, 1985).

10/29/86
Date

Adriano R. Gabuter
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10/29/86
Date

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Attachment