Finding of No Significant Impact (FONSI)
for
Pulmotil 90 Type A Medicated Article
(tilmicosin)
in
Cattle

ELANCO Animal Health
Greenfield, IN

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.

Elanco Animal Health is requesting the approval of a new animal drug application (NADA) for the use of Pulmotil 90 Type A Medicated Article (tilmicosin) in cattle. The product is proposed for use at a targeted dose of tilmicosin up to 12.5 mg /kg/day in the feed of cattle for the control of bovine respiratory disease (BRD) due to *Mannheimia haemolytica*, *Pasteurella multocida* and/or *Histophilus somni* in groups of cattle experiencing an outbreak of BRD.

Tilmicosin is currently approved for feed use in swine under NADA 141-064 for the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* and for injectable use in sheep, beef and dairy cattle, excluding female breeding age animals, for the control of BRD associated with *P. haemolytica* and sheep for the control of ovine respiratory disease associated with *M. haemolytica* under NADA 140-929. EAs and FONSIs for the feed and injectable uses of tilmicosin in swine and cattle are available on-line at the Center for Veterinary Medicine website under Freedom of Information tab.

In support of the application, Elanco has provided an environmental assessment (EA) signed October 22, 2008. A copy of the EA is attached.

The EA provides information on the potential introduction and expected environmental exposures for the proposed use of Pulmotil 90 Type A Medicated Article. The EA evaluates the proposed use relative to the Center for Veterinary Medicine's Guidance for Industry #166 (Environmental Impact Assessments for Veterinary Medicinal Products – Phase II).

The EA adequately characterizes the potential introductions and fate of tilmicosin in the environment and provides predicted environmental concentrations (PECs) from single and multiple applications of manure containing tilmicosin to agricultural soils. The EA also provides endpoint data on the toxicity of tilmicosin to index species for microbes, plants, invertebrates, and vertebrates that could be exposed to tilmicosin in soil and runoff from agricultural fields. The biological predicted no effect concentration (PNEC) for earthworm chronic and reproductive toxicity is more appropriately characterized at 31,000 µg/kg rather

than the 100,000 µg/kg currently used in the EA, but even at the lower PNEC, effects to this species are not anticipated. Comparison of the remainder of the PECs and PNECs also finds that toxic effects are not expected to occur.

Although the EA mentions the potential for tilmicosin to be introduced into the environment from spillage and breakage of containers, there is no attempt in the EA to include this introduction in the PECs. Relative to the total amount predicted to be introduced to the environment from the proposed use, it is expected that the amount introduced from breakage and spillage will not significantly changed the PECs or the conclusions of this FONSI.

Based on the information in the EA, no significant environmental impacts are expected from the proposed use of tilmicosin in cattle. We have reviewed the EA and find that it supports a FONSI.

May 20, 2009
Date

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

cc: Document Control Unit, for the administrative file of:
[redacted]
HFV-103 Reading

Concurrence	Final Signature and Date
Donald A. Prater, DVM Director, Division of Scientific Support, HFV-160	5/20/2009
Charles Eirkson Expert Reviewer and Team Leader, Environmental Safety Team, HFV-162	5/20/2009