



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUL 8 2003

ANADA 200-348

\*David Petrick, VMD, JD  
Senior Director, Worldwide Regulatory Affairs  
Schering-Plough Animal Health Corporation  
1095 Morris Ave.  
Union, N.J. 07083

Dear Dr. Petrick:

This letter is in reference to an advertisement for your product, CooperMEC™ Pour-On for Cattle, ANADA 200-348, found in the March/April 2003 issue of Feedlot magazine. The advertisement states the product comes with a product satisfaction guarantee: "Schering Plough Animal Health will honor this guarantee of lice coverage for six months following treatment with CooperMEC™ against the lice species indicated on the product labeling, provided the product is used in accordance with label directions and certain procedures are followed."

The six-month guarantee for lice coverage is evidence that the product is intended to be used for persistent activity for lice. The product is approved with the indication to treat existing lice infestations. The 180-day guarantee goes beyond claiming treatment of existing lice infestations; it suggests that the product is safe and effective in treating persistent lice activity (i.e., lice activity over the 180-day guarantee period following treatment), a claim that is beyond the scope of the approved labeling. A product's labeling must have adequate directions for use, which includes statements of all conditions, purposes, or uses for which the drug is intended (21 CFR 201.5). Because the claim regarding the persistent lice activity is not adequately provided in the "directions for use" section of the product labeling, your product is misbranded under section 502(f) of the Federal Food, Drug, and Cosmetic Act.

We wish to remind you of the commitment you made when you signed the Abbreviated New Animal Drug Application Form, FDA 356V, that you will promote your product only in accord with the labeling provided for in the currently approved application. We request that you immediately cease dissemination of the 180 day lice guaranty information and any related materials.

Please inform us of your intentions regarding this matter within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM, M.Sc.  
Team Leader, Marketed Product Scientific  
and Regulatory Review Team II, HFV-216  
Division of Surveillance  
Center for Veterinary Medicine