



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 27 2001

• ANADA 200-219

Mr. Robert D. Gunderson
Vice President of Regulatory Affairs
Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joeseph, MO 64503

Dear Mr. Gunderson:

We are referring to the promotional piece of your distributor [redacted] for [redacted] Pour-On (ANADA 200-219) entitled: "[redacted] 6 Month Lice Guarantee." The promotion is guaranteeing the use of [redacted] as being effective against biting and sucking lice for 180 days. "The guarantee remains in effect even when untreated animals are co-mingled with treated animals-for up to 45 days following treatment." The piece then provides the following disclaimers:

- 1.) All animals entering the same confined pen or pasture must be treated within a four-day period.
- 2.) Between June 1 and December 31, 2001, every animal must be treated with a fall lice treatment of [redacted] according to dosage and application recommendations stated on the label.
- 3.) Claims for lice infestation following treatment must be submitted within 180 days of product purchase.


We consider the 180 days lice free guarantee cited above to be outside the scope of the labeling provided for in the approved new animal drug application. There are no data submitted to this ANADA to support persistent action or residual effect for up to 180 days. In fact, the evidence contained in the Pioneer's approved application is only supportive of effectiveness of the product for up to 56 days. The [redacted] promotional piece therefore, making such unsubstantiated claims causes your product to be misbranded under Section 502 (a) of the Act.

We wish to remind you of the commitment you made when you signed the Abbreviated New Animal Drug Application Form, FDA 356V, that your product will be promoted only in accord with the labeling provided for in the approved application. As a sponsor of the ANADA, Phoenix Scientific has the ultimate responsibility to ensure that promotion/advertising by the company or by its agents/distributors do not violate the conditions of the approved application. We suggest that you give due consideration and attention to the promotional practices of the distributors of your product(s) to ensure that their promotional materials comply with the requirements of the Act and the promotion and advertising regulations.

Should you or your distributor wish to use these claims in the future promotional materials, we recommend that you submit the supporting data in a supplemental new animal drug application to HFV-130 (ONADE) for the Center's formal review and approval. In the meantime, we request that you have your distributor [REDACTED] immediately stop the distribution of the cited material and advise them to promote your product only in accord with the approved labeling.

Please inform us of your intentions as soon as possible or in any event within 30 days of the date 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