DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 22 2000

NADA 141-095

Tracey Rockney, JD
Associate Director, Regulatory Affairs
Animal Health Group
Pfizer Inc.
812 Springdale Drive
Exton, PA 19341-2803

Dear Ms. Rockney:

We have revisited your several promotional pieces submitted on October 22,1999, and October 25,1999, concerning DECTOMAX Pour-On solution for cattle, NADA 141-095.

The promotional piece, entitled "Pour-on protection that's more than skin deep" coded, DX9970/799 9-1464, and the promotional piece entitled "The only product made with doramectin- the superior science molecule providing persistence that pays" make statements such as, "Pfizer's exclusive LiceTime Guarantee program: (a) offers 45-day pen/pasture filling – that's more than 10 times the flexibility you get from other pour-ons. (b) ensures satisfaction with your Dectomax Pour-On lice control program for up to 365 days." In addition, the promotional material entitled, "Dectomax Pour-On versus ivermectin pour-ons. The difference is black & white " coded DXP0999056 states that: " 10 times the flexibility –you get 45 days from beginning to end to treat a pen of cattle. Guaranteed, season-long lice control (even if you treat in August)."

We consider the 365 days lice free guarantee and other claims cited above to be out side of the scope of the labeling provided for in the approved new animal drug application. For example, there are no data submitted to this NADA to support a persistent action or a residual effect up to 365 days. In fact, the evidence contained in the approved application is only supportive of effectiveness of the product for up to 35 days. Also the introduction of new animals to a previously treated group in a pen or on a pasture may be problematic. These promotional pieces make unsubstantiated claims, and therefore, cause your product to be misbranded under Sections 502(a) of the Act.

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA 356V, that you will promote your product only in accord with the labeling provided for in the approved application. In addition, we suggest that you give due consideration and attention to your company's promotional practices to ensure that your promotional materials comply with the requirements of the Act and the promotion and advertising regulations.

Should you wish to use these claims in your future promotional materials, we recommend that you submit the supporting data in a supplemental new animal drug application to HFV-130 for Center's formal review and approval. In the meantime, we request that you immediately stop using the cited material and 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