DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV - 3 2000

NADA 140-841

Rosalind S. Dunn
Associate Director
Approved Products Records & Reports
Regulatory Affairs
Merial Limited
2100 Ronson Road
Iselin, NJ 08830-3077

Dear Ms. Dunn:

We have revisited your submission dated May 7, 1999, which contained several promotional pieces concerning IVOMEC Pour-On for Cattle, NADA 140-841. The promotional piece "IVOMEC Pour-On for Cattle: Lice Free Guarantee Program" coded IVC-9-1009.2., 505-FDP, includes statements such as, "Use IVOMEC (ivermectin) Pour-On on your entire herd or pen for your fall/winter treatment and be covered by Merial's Lice-Free Guarantee Program. This is a 100% Satisfaction Guarantee." The promotional piece, entitled "Satisfaction ... Guarantee; 100% Satisfaction in Lice Control ... from IVOMEC Pour-On" and Up to One-Year Satisfaction Guarantee, coded, IVC-91009.2.504-DPD, makes statements such as, "IVOMEC Pour-On has a new flexible 100% Lice Free Satisfaction Guarantee!" and that "Producers can process and add cattle to a pen/pasture according to their schedule. No need to separate groups of cattle processed days, weeks, even months after the initial treatment with IVOMEC Pour-On." The promotion also guarantees Lice control for 365 days.

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 56 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 making such unsubstantiated claims therefore, cause your product to be misbranded under Sections 502(a) and adulterated under 501(a)(5).

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