



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 12 2004

NADA 140-841

UNTITLED LETTER

Liubov Skibo
Associate Director, Regulatory Affairs
Support & Liaison
Merial Limited
3239 Satellite Boulevard
Building 500 Ste. 108A
Duluth, GA 30096

Dear Ms. Skibo:

We refer to your two submissions dated September 8, 2003, for IVOMECE® (ivermectin) Pour-On for Cattle, NADA 140-841, containing promotional materials. The promotional items in question include: two shelf talkers (#RAGEBPO300A (4/03) & #RAGEBPO300B (4/03)) and a product detailer (#RAGEPP0312 (5/03)).

The claims in the above materials include:

- IVOMECE® (ivermectin) Pour-On can improve ear tag efficacy
- Make ear tags work longer against horn flies
- For horn-fly control, IVOMECE Pour-On makes a perfect tag-teammate.
- 100% Lice Control
- Up to 56 days of control of biting and sucking lice

We are unaware of any data to support the above listed claims. Your materials are misleading because they present claims for IVOMECE® that are not consistent with those provided for in the currently approved labeling. Your current approved product label does not contain any persistent activity claims for biting or sucking lice, nor does it demonstrate 100% efficacy for lice. Additionally, your current approved product label does not mention concurrent use of organophosphate ear tags with the product. These statements are false and misleading, causing your product to be misbranded under Section 502(a) of the Act.

We request that you immediately stop dissemination of the above materials and any other similar promotional material. Please inform us of your intentions 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
Post-Approval Review Team, HFV-216
Division of Surveillance
Center for Veterinary Medicine