



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 13 2000

NADA 038-233

Nancy Thompson-Brown
Regulatory Compliance Specialist
Schering-Plough Animal Health Corp
1095 Morris Avenue
Union, NJ 07083

Dear Ms. Thompson-Brown,

We refer to your submission for Ralgro (zeranol) NADA 038-233, dated October 12, 2000. The submission included two print advertisements "All Implants Add Weight" and "Performance on the Range".

In both ads, the following statement appeared "Only Ralgro consistently demonstrated a minimal effect on quality grade, while improving both feed efficiency and weight gain." The advertisement "All Implants Add Weight" also stated "Only One Preserves Beef Quality". The drug product is approved for "increased rate of weight gain and improved feed conversion." These ads make reference to preservation or improvement in "quality grade" which is deemed an unapproved claim, therefore causing your product to be adulterated under 501(a)(5) and misbranded under 502(a) of the Act.

You are reminded of the commitment you made when you signed the New Drug Application Form, FDA-356-V, that you will promote your product only in accord with the labeling provided for in the approved application. We request that you discontinue using these promotional materials immediately. In addition, we suggest that you give due consideration and attention to your company's promotional practices and ensure that your promotional materials comply with the requirements of FDA regulations.

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

Sincerely yours,

MA



Mohammad I. Sharar, DVM, M.Sc.
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And Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine