



DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV 15 2000

Food and Drug Administration
Rockville MD 20857

NADA 038-233

Nancy Thompson-Brown
Regulatory Compliance Specialist
Schering Plough Animal Health Corp
1095 Morris Avenue
P.O. Box 3182
Union, New Jersey 07083

Dear Ms Thompson-Brown:


We refer to your submission dated August 14, 2000, for Ralgro (zeranol), NADA 038-233. The submission included three promotional labeling pieces, SPAH-RAL-73, "Key Points About Ralgro...", RAL-81A "Wheels for Bucks", and RAL-81C "Turn Those Wheels Over".

We find the promotional pieces, SPAH-RAL-73 and RAL-81C misleading because they failed to provide information relating to the side effects and cautions in the same language and emphasis contained in the approved labeling as stipulated under 21 CFR 201.105(d)(1). Additionally, SPAH-RAL-73, "Key Points..." states "...implant sites reactions occurred in only 1.56% of cattle implanted with Ralgro but 6.35% of cattle implanted with Synovex-S." According to the study cited in the piece, "Comparison of feedlot performance and carcass traits of steers administered anabolic implants and anthelmintic drenches" however, the percentage of implant site reactions with Synovex was shown to be 6.25%. Therefore, the promotional piece, SPAH-RAL-73 making false and misleading representations with respect to another drug, causes your product to be misbranded under 21 CFR 201.6(a).

We request that you discontinue any further distribution of these promotional pieces. In addition, we request that you review your company policies to ensure that your promotional materials comply with the requirements of FDA's drug promotion and advertising 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,


Mohammad I. Sharar, DVM., M.Sc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
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