DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 5 2000

NADA 131-310

William D. Lewis, MS
Regulatory Specialist-Pharmaceuticals
Intervet America, Inc.
405 State Street
P.O. Box 318
Millsboro, Delaware 19966-0318

Dear Mr. Lewis:

We are referring to your Special Drug Experience Report of July 24, 2000, for Regu-Mate, Altrenogest, NADA 131-310. The submission included two pieces of Promotional Labeling and one Print Advertisement which appeared in the July 2000 issue of Equus Magazine (pages 9-10). The advertisement failed to present a fair balance of information relating to the side effects and contraindications with a prominence, depth and detail reasonably comparable with the presentation of information relating to the effectiveness of the drug in the body of the advertisement [21 CFR 202.1(e)(5)(ii)]. In addition, the brief summary and the ad do not include the name and address of the manufacturer as required by Section 502(b) of the Act.

We request that you stop using this advertisement immediately. We recommend that you review your company policies to give due consideration and attention to promotional practices and ensure that your future promotional materials comply with the requirements of FDA regulations.

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, MSc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV- 216
Division of Surveillance
Center for Veterinary Medicine