



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 2 2002

NADA 141-087

Andrew T. Palmeter, DVM
Associate Director, Regulatory Affairs
Cyanamid Agricultural Research Center
P.O. Box 400
Princeton, NJ 08543-0400

Dear Dr. Palmeter:

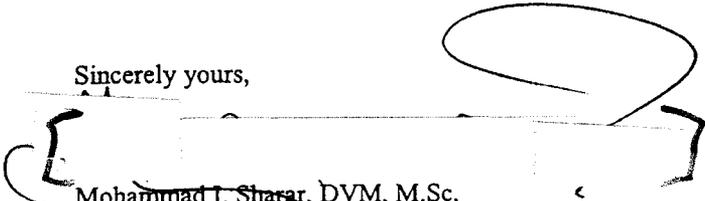
This is in reference to your submission dated September 27, 2001, concerning Moxidectin, NADA 141-087. This submission includes Clinical Data and Promotional Labeling. We refer to the detailer piece FDP#E0018T entitled: "The Next Generation of Equine Parasite Control." On the 6th page of the detailer, under the "Proven Safety - Test After Test" section, the piece suggests safety in foals by stating that: "Foals administered 2 and 3 times normal dose - no significant signs of toxicity" followed by a supportive testimonial by Dr. [redacted] VMD, Ph.D., [redacted] researcher. The endorsement does not identify the age of the foals that were dosed in the study which implies safety in foals, regardless of age. This information is inconsistent with the currently approved labeling, which contains a warning against use in foals under 4 months of age.

We consider an endorsement for use in foals, without identifying age and in excess of the recommended dose, within the text of a promotional labeling piece to be outside the scope of the labeling provided for the new animal drug application. In fact, our Adverse Drug Experience (ADE) reports support the lack of safety in foals less than 4 months of age, particularly in the case of overdose.

We 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 in the approved application. We request that you discontinue the detailer piece in question and refrain from using such information in your future promotional labeling.

Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301) 827-4462.

Sincerely yours,


Mohammad I. Sharaq, DVM, M.Sc.
Team Leader, Marketed Product Scientific
and Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine