



MAR 24 2003

• NADA 141-068

Douglas Rupp, Director
Pharmaceutical Regulatory Affairs
Bayer Corp Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201

Dear Douglas Rupp:

This is in reference to your Drug Experience Report (DER) submission dated October 23, 2002, concerning Baytril 100 (enrofloxacin), NADA 141-068. This submission includes Promotional Labeling.

Your "Dear Cattle Practitioner" letter (included with your submission) compares the pivotal studies used for the FDA approval of Baytril 100 with those pivotal studies used for the FDA approval of [] and implies that Baytril 100 is more effective than []. Your letter suggests that the pivotal study for [] was not adequate to demonstrate effectiveness. However, based on the data submitted by [], FDA has determined that [] is safe and effective for its indications for use. Both of these drugs are FDA approved as safe and effective for their respective indications for use. Therefore any claim of superiority for Baytril 100 over [] is false and misleading.

We request this and any similarly misleading promotions be stopped immediately.

Please respond as soon as possible or in any event 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,

[]

Martine Hartogenesis, DVM
Acting Team Leader, HFV-214
Division of Surveillance
Center for Veterinary Medicine