



OCT 12 1999

NADA 141-068

Ms. Diane Lavenburg
Director, Pharmaceutical Regulatory Affairs
Bayer Corporation
Agricultural Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201

Dear Ms. Lavenburg:

We have become aware of an advertisement for Baytril® 100 (enrofloxacin), which appeared in the September 6, 1999, issue of *The High Plains Journal The Farmer-Rancher Paper*. We have reviewed this advertisement and find it to be violative.

The advertisement is violative because it makes several effectiveness claims in the body of the ad, yet fails to provide any balance with risk information [21 CFR §202.1(e)(5)(ii)]. The approved professional labeling has several prominent warnings bound by compressed arrows, in addition to a prohibition against extra-label use in food-producing animals, yet none of this important risk information appears in the text of the ad. The advertisement may also be lacking in fair balance, or otherwise misleading because it fails to present the summary of information relating to side effects and contraindications, with a prominence and readability reasonably comparable with the information relating to effectiveness, taking into account all implementing factors such as typography, layout, contrast, white space, and any other techniques apt to achieve emphasis [21 CFR §202.1(e)(7)(viii)]. Additionally, our records do not indicate that Bayer Corporation submitted the advertisement on Form FDA 2301 at the time of initial publication, thus Bayer has violated the postmarketing reporting requirements [21 CFR §510.300(b)(3)].

We ask that this advertisement and similar promotional material being used or intended to be used in the future be immediately stopped. In addition, we request that you review your company policies to give due consideration and attention to promotional practices and ensure that your promotional materials comply with the requirements of FDA regulations.

Please inform us of your intentions within 15 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6639.

Sincerely yours,



Violis Vengris, D.V.M., Ph.D.
Marketed Product Scientific and
Regulatory Review, Team 1, HFV-214
Division of Surveillance
Center for Veterinary Medicine