



SEP 16 1999

NADA 140-913
NADA 140-441

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 reviewed several promotional materials for Baytril® (enrofloxacin), NADAs 140-441 and 140-913. Specifically, they are: 1) Baytril (enrofloxacin) advertisement (January 1999/81018810/R.9); 2) Detailer B99113; 3) File folder for review articles (B99182) with review article, issue one, "The Smart Antimicrobial."; and 4) Baytril Injection of Knowledge: Tablets & Injectable (B99258).

The advertisement fails to present any risk information in the body of the text and thus lacks fair balance [21 CFR §202.1(e)(5)(ii)]. In addition, the brief summary should appear as an integral part of the advertisement, which this advertisement fails to do. The advertisement appears on page 4 while the brief summary appears on page 34. To achieve acceptable balance, the brief summary should be placed on the same page as the advertisement, or within one turn of a page either preceding or following the advertisement. Also, 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)].

Items 2, 3, and 4 are deemed labeling. Promotional materials may be lacking in fair balance if they fail to present important risk information in the body of the text. The aforementioned promotional materials contain the claims, "BAYTRIL® HAS CONSISTENTLY PROVEN TO BE CLINICALLY SUCCESSFUL IN THE TREATMENT OF: ...," "Baytril® (enrofloxacin) and its exceptional performance against a variety of pathogens," and "Rapidly kills the main urinary pathogens in vivo." trigger the need for balancing with risk information, which these items fail to do.

We ask that the advertisement and dissemination of promotional material cited in this letter and other similar 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,



Vitolis Vengris, D.V.M., Ph.D.
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