



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 10 1999

NADA 140-929

Bruce W. Martin, DVM, Ph.D.
Elanco Animal Health
Manager, Regulatory Affairs
2001 W. Main Street, DC GL21
Greenfield, IN 46140

Dear Dr. Martin:

We have become aware of two advertisements for Micotil®, NADA 140-929: 1) a two-page advertisement which appeared in the October 1999 issue of *Beef magazine* entitled "a little bit sick? there's no such thing;" and 2) a similar advertisement on page 43 of the September 1999 *Bovine Veterinarian* magazine entitled "you may be nickeling and diming him to death." We have reviewed these advertisements and find them to be in violation of the prescription drug advertising regulations [21 CFR §202].

The advertisements are deemed violative because they are not fairly balanced. The advertisements make effectiveness claims in the body of the advertisement, yet fail to provide any balance with the risks associated with use of the drug [21 CFR §202.1(e)(5)(ii)]. The approved professional labeling includes important warnings and contraindications, yet none of the important risk information appears in the body of the advertisement. Fair balance is not achieved merely by including a brief summary or approved professional labeling.

We ask that these advertisements and similar promotional material being used or intended to be used in the future be immediately stopped. 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.
Marketed Product Scientific and
Regulatory Review, Team 1, HFV-214
Division of Surveillance
Center for Veterinary Medicine