DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 12 1999

NADA 140-929

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

Dear Dr. Martin:

We refer to your Drug Experience Report dated August 20, 1999, for Micotil® 300 (tilmicosin phosphate Injection), NADA 140-929. The submission included a promotional brochure titled "MICOTIL MODE OF ACTION," coded AI# 8726 (8/99) , which is considered labeling as stipulated under 21CFR 202.1 (l)(2).

In this brochure, Elanco presents information that Micotil's effectiveness is contributed to its achieving significant concentrations within macrophages and neutrophils, and then being recruited to the site of infection, in this case the lung. Elanco then suggests that the presence of Micotil in these recruited cells, and then bacteria, results in apoptosis (rather than cell necrosis), which reduces the incidence of inflammation and tissue damage in the lung. However, Elanco does not provide the context for this information – that this is, to our knowledge, based on *in vitro* data and that *in vitro* data are not always indicative of clinical effectiveness. Further, *in vitro* data used in a way to suggest that they have clinical significance when in fact no clinical significance has been demonstrated is false or misleading. We remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356 V, that you will promote your product only in accord with the labeling provided for in the approved application.

Additionally the brochure fails to present a balance of information in the body of the text. That is, the efficacy information in the body of the text not fairly balanced with risk information , as required under 21 CFR 202.1(e)(5)(ii). The use of a statement such as , "...Helps cattle with BRD recover more quickly and with less lung damage..." triggers the need for balancing with risk information.

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

Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

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