



OCT 25 1999

NADA 141-063

Ms. Celia C. Castaneda
Regulatory Compliance Specialist
Schering-Plough Animal Health
1095 Morris Avenue
Union, NJ 07083

Dear Ms. Castaneda:

We refer to your Drug Experience Report dated August 12, 1999, concerning Nuflor®, NADA 141-063. Specifically, we refer to the Technical Update entitled, "A Comparison Of Florfenicol And Tilmicosin For Bovine Respiratory Disease Treatment In The Feedyard," SPAH-NFL-276.

The submitted piece is deemed labeling as stipulated under 21 CFR §202.1(l)(2). Specifically, we have reviewed this piece and find it to be misleading. Schering-Plough Animal Health (SPAH) has published a promotional piece which makes misleading product comparisons between Nuflor® (florfenicol) and Micotil® (tilmicosin) based on data obtained from the paper "A comparison of florfenicol and tilmicosin for the treatment of undifferentiated fever in feedlot calves in western Canada" (1). The promotional piece is misleading for the following reasons:

- The purpose of the investigation was to compare the therapeutic efficacy of florfenicol and tilmicosin for the treatment of bovine respiratory disease (BRD) complex in feedlot calves that received metaphylactic tilmicosin upon arrival at the feedlot. The pretreatment of one study group creates a bias in the study data. SPAH has neglected to convey this important information in the proper context in relation to the "more effective treatment" claim for Nuflor®. In addition, the authors state in their conclusion that "extrapolation of these results to other populations may not be appropriate." Therefore, based on this study there is lack of substantial evidence to support your superiority claim.
- There is inconsistency in data. SPAH indicates that a lower incidence (7%) of *P. haemolytica* in the Nuflor® group, and that this finding is significant because Micotil® is labeled only for treating *P. haemolytica*, yet the Micotil-treated group harbored more *P. haemolytica* than the Nuflor® group. However, SPAH fails to mention that each experimental animal received a *P. haemolytica* bacterin/toxoid. Thus, the presentation of these data is misleading. Also, in the promotional piece (Table 1. Morbidity and Mortality Summary), the number of calves identified as dying from BRD is quoted as 10 for Nuflor® and 27 for Micotil®, yet the microbiological data from the paper (Table 4. Microbiological data summary by experimental group) from lung tissue is from a data set of 15 for Nuflor® and 37 for Micotil®.

This is not necessarily an exhaustive list of possible objectionable information. We ask that the above referenced item and those containing the same or similar misleading statements cease immediately. 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) 827-6639.

-
1. Jim, G.K., Booker C.W., et.al. A comparison of florfenicol and tilmicosin for the treatment of undifferentiated fever in feedlot calves in western Canada. Can Vet J. Volume 40, March 1999/179-184.

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