



August 28, 1998

NADA 141-108

Ms. Debra Webb  
Manager, Pharmaceutical Regulatory Affairs  
Fort Dodge Animal Health  
Division of American Home Products  
800 Fifth Street, N.W.  
Fort Dodge, IA 50501

Dear Ms. Webb:

This is to confirm our telephone conversations with you on August 24, 1998, and also with Mr. Andy Palmeter on August 25, 1998, concerning the promotional material that was submitted on August 19, 1998, for Etogesic (etodolac), NADA 141-108. The material was distributed last week by Fort Dodge in support of the launch of Etogesic.

We discussed with you the gravity of the problem and the serious concerns we have with the promotional material. We requested that any further distribution of this highly objectionable promotional material be stopped immediately. In a subsequent telephone conversation on August 25, 1998, Mr. Palmeter confirmed that Fort Dodge has complied with our request and the distribution of the material has been stopped.

We greatly appreciate your cooperation in this matter.

We intend to respond formally by a letter explaining our objections to the material at a later date.

Sincerely yours,

Mohammad I. Sharaf, D.V.M., M.Sc.  
Team Leader, Marketed Product Scientific  
and Regulatory Review Team II, HFV-216  
Division of Epidemiology and Surveillance  
Center for Veterinary Medicine