DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 17, 1998

REGISTERED MAIL

NADA 141-082

Judith E. Spiegel, Ph.D.
Director, Regulatory Affairs
Heska
1825 Sharp Point Drive
Fort Collins, CO 80525

Dear Dr. Spiegel:

We refer to your August 11, 1998, letter regarding promotional materials that were submitted as part of a DER submission. These promotional pieces consist of an advertising piece and video both entitled "Introducing The Heska Periodontal Disease Therapeutic," a Technical Bulletin entitled "Periodontal Disease: Diagnosis, Treatment, and Control," and two reprints submitted in support of the promotional material. You request our permission to continue the use of these promotional materials until the material in question would be exhausted in a period of five months.

We cannot grant your request since claims for doxycycline hyclate are not provided for in the approved application and are not in compliance with 202.1(d)(6)(vii) which states, " An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the Act, among other reasons, if it: contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated." The conclusions from both of the studies you refer to were based on in-vitro and rat studies, which are not acceptable.

We do not agree with you that the unapproved claims are not a major component or emphasis in the marketing of your product. The Technical Bulletin lists these properties of tetracycline, including doxycycline, directly under the antimicrobial properties with the use of bullets and italics which emphasizes the unapproved claims. Therefore, it would be inappropriate to grant you permission to continue using these promotional pieces.

We again request that further distribution of this material be discontinued.

Sincerely yours,

Vitolis E. Vengris, D.V.M., Ph.D.
Team Leader, Marketed Product
Scientific and Regulatory Review Team
Division of Epidemiology
and Surveillance
Center for Veterinary Medicine

DEPARTMENT OF HEALTH & HUMAN SERVICES

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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. Sharar, 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