DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 27 2003

NADA 141-108

Ann Hokinson, Assistant Manager, Pharmaceutical Regulatory Affairs
Fort Dodge Animal Health, Division of Wyeth
141 East Riverside Drive
PO Box 518
Fort Dodge, IA 50501

Dear Ms. Hokinson,

This is in reference to your submission dated January 30, 2003, concerning **EtoGesic Tablets, NADA 141-108**. This submission includes two videotape copies of a television commercial for EtoGesic use in dogs.

We refer to the portion of the commercial where the woman offers the EtoGesic tablet to the dog and the dog appears to willingly ingest it from her hand. In approving oral dosage form products, we distinguish between tablets and chewable tablets. Supporting data for the latter is usually a palatability study demonstrating that dogs will willingly consume the chewable tablets and thereby receive an effective dose. Because Etodolac is not approved as a chewable formulation, and we are not aware of data supporting this formulation, we consider this scene to be misleading in implying that the tablet is chewable.

The announcer states, "The most commonly reported side effects with EtoGesic Tablets include vomiting, lethargy and diarrhea." The television commercial fails to mention, in audio or audio and video parts, other major side effects as required by 21 CFR § 202.1(e)(1). Major side effects on the approved product labeling include death, convulsions, kidney failure, liver disease, dyspnea, keratoconjunctivitis sicca, and coagulation disorders.

The announcer concludes by saying that, "Pets on any medication should be regularly monitored. Ask about EtoGesic." These statements do not specify who should regularly monitor the pets or who the listener should ask about Etogesic. We recommend the announcer clearly state that regular monitoring be conducted by a veterinarian. As this is a prescription product, we recommend the consumer be instructed to "Ask *your veterinarian* about EtoGesic."

We request that you stop showing this television commercial immediately and revise your future promotional material in accord with our comments and recommendations. Please inform us of your intentions within 30 days of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

John D. Baker, D.V.M.
Acting Team Leader, Marketed Product Scientific
and Regulatory Review Team I, HFV-214
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