



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 22 2003

*NADA 141-108

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

Dear Ms. Hokinson:

We refer to your promotional detailer (FDP#C0117D) for EtoGesic® (Etodolac), NADA 141-108, which has recently come to our attention.

The promotional piece contains several statements suggesting that EtoGesic is more effective than and

Specifically, statements such as "No other NSAID has been proven to ... work faster, or last longer" suggest that EtoGesic is superior to other approved non-steroidal anti-inflammatory drugs (NSAIDS) for dogs. This drug comparison represents or suggests that your product is more effective than and because it "works faster" and "lasts longer." We are not aware of substantial evidence or substantial clinical experience to support this claim. For this reason, the comparison you have presented is false or misleading. 21 CFR 202.1(e)(6)(ii).

Furthermore, your graphs showing that "peak plasma concentrations" are reached in a shorter time period and that your product has a longer half-life period than other products are presented as your bases for concluding that your product is "fast acting" and "long lasting," respectively. We are unaware of any scientific data demonstrating a correlation between the pharmacokinetic data in these graphs and clinical effectiveness, including how fast the product "acts" and how long its effect lasts. Your use of favorable data or conclusions from nonclinical studies in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated is false or misleading under 21 CFR 202.1(e)(6)(vii).

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA 356V, that you will promote your product only in accord with the labeling provided in the currently approved application.

Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt date of this letter. If you have any questions, you may contact us at (301)827-6642.

Sincerely yours,

John D. Baker, D.V.M.
Team Leader, Marketed Product Scientific
and Regulatory Review Team I, HFV-214
Division of Surveillance
Center for Veterinary Medicine