



SEP 3 1999

NADA 141-038

Ms. Barbara Goulding
Regulatory Associate
Regulatory Affairs
Luitpold Pharmaceuticals
One Luitpold Drive
Shirley, New York 11967

Dear Ms. Goulding

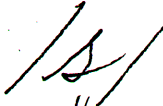
We have become aware of an advertisement which appeared in the July 1999, edition (page 21) of Veterinary Forum for Adequan ® Canine, NADA 141-038.

We note that the advertisement fails to present a fair balance of information relating to side effects and contraindications with a prominence, depth, and detail reasonably comparable with the presentation of information relating to the effectiveness of the drug in the body of the advertisements as required under 21 CFR §202.1(e)(5)(ii). In particular, the advertisement emphasizes the benefits of the drug stating that unlike other joint therapies that only reduces pain and inflammation, Adequan Canine is the only joint therapy proven to modify the disease, altering the course of degenerative joint disease and stimulating cartilage repair processes. But it fails to present a true statement of information in the running text of the ad relating to side effects and contraindications listed in the approved labeling.

We ask that the advertisement cited in this letter, and other similar ones intended for future dissemination, be immediately stopped. In addition, we request that you give due consideration and attention to your promotional practices and ensure that the promotional materials comply with the requirements of FDA regulations.

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) 827-6642.

Sincerely yours,



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And Regulatory Review Team II, HFV-216
Division of Surveillance
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