

JUL 17 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 another advertisement which appeared in the August 1999th edition of *DVM News Magazine* (page 426) for Adequan ® Canine (NADA 141-038).

This is the second advertisement within a few months (refer to CVM letter dated 9/3/99) that 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 [21 CFR §202.1(e)(5)(ii)]. The approved indications for Adequan Canine are: "for the control of signs associated with non-infectious degenerative and or traumatic arthritis" but this ad promotes unapproved indications. Your ad incorrectly states that "Adequan Canine is the only joint therapy proven to modify the disease, altering the course of degenerative joint disease and stimulating cartilage." These indications or claims do not appear in the approved label. The ad also neglects to give the generic drug name in conjunction with the trade name. The brief summary is not mentioned in the ad and appears 21 pages away from the advertisement (page 447). The brief summary should appear on the same page as the advertisement or at the most within one turn of a page either preceding or following the advertisement.

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

Please inform us of your intentions within 15 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6639.

Sincerely yours,

Mohammad I. Sharaf, DVM, MSc
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