



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

AUG 17 2007

- NADA 140-901 (L 110)
- NADA 136-383 (L 94)

Barbara Goulding  
Manager, Regulatory Affairs  
Luitpold Pharmaceuticals, Inc  
One Luitpold Drive  
Shirley, NY 11967

**RE: NADA 140-901 and 136-383 Adequan® (polysulfated glycosaminoglycan);  
promotional labeling piece: AHD3007**

Dear Ms Goulding.

The Center for Veterinary Medicine (CVM) has reviewed a reprint piece originally published in The National Reining Horse Association and NRHA Reiner, Volume 26, Issue 11. The piece was submitted to CVM in a special Drug Experience Report (DER) dated April 9, 2007. This piece promotes Adequan® i.m., NADA 140-901, and Adequan® i.a., NADA 136-383, for new intended uses that are not the subject of approved new animal drug applications (NADAs). When promoted for these new, unapproved intended uses, Adequan® i.m. and Adequan® i.a. are unsafe within the meaning of section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 360b(a)(1)] and adulterated under section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)]. In addition, the promotional piece is false or misleading because it fails to reveal any risk information for Adequan® i.a. Adequan® i.a., is therefore misbranded within the meaning of section 502(a) [21 U.S.C. 352(a)] and 201(n) [21 U.S.C. 321(n)] of the Act.

**Background**

Adequan® i.m. is an injectable polysulfated glycosaminoglycan indicated for use in horses. Its labeled indication is for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints.

Adequan® i.a. is an injectable polysulfated glycosaminoglycan indicated for use in horses. Its labeled indication is for the intra-articular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal joint.

## Promotion for New Intended Uses

In the section entitled “The Balanced Joint,” this promotional piece presents two quotes by a horse trainer: 1) “...If we have a problem, it’s generally a series of seven shots of Adequan®, four days apart, and then we go to every other week for injections.” 2) “In competition like the NRHA Reining Futurity, we’ll give a shot of Adequan® every day.” The approved dosage of Adequan® i.m. is 500 mg every 4 days for 28 days intramuscularly. These statements promote the drug for an unapproved, more frequent dosage (every other week or daily). This more frequent dosage represents a new intended use that requires approval of a supplemental NADA. Promotion of Adequan® i.m. for this new intended use without an approved NADA renders the drug unsafe under section 512(a)(1) of the Act [21 U.S.C. 360b(a)(1)] and adulterated under section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)].

In the section entitled “Maintaining the Superstar,” this promotional piece states “In joints requiring injection, [a veterinarian] regularly uses Adequan® i.a. in stifles and fetlocks.” The veterinarian is then quoted as saying, “In these intra-articular injections, if we’re treating cartilage lesions or arthritis, we use Adequan® i.a.” Adequan® i.a. is only approved for use in the carpal joints of horses. It is not approved for use in the stifle and fetlock joints. Promotion of Adequan® i.a. for this new intended use without an approved NADA renders the drug unsafe under section 512(a)(1) of the Act [21 U.S.C. 360b(a)(1)] and adulterated under section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)].

## Omission of Risk Information

As noted above, the section of the promotional piece entitled “Maintaining the Superstar” promotes the use of Adequan® i.a. for treating cartilage lesions and arthritis in horses. The approved labeling for Adequan® i.a. contains the following **Contraindications**: “Do not use in horses showing hypersensitivity to polysulfated glycosaminoglycan. Do not administer Adequan in the face of joint sepsis.” The approved labeling also contains the following **Adverse Reactions**: “Two major categories of adverse reactions have been reported following the intra-articular administration of Adequan: 1) Inflammatory joint reactions consisting of joint pain, effusion, and swelling with associated lameness, and 2) Septic arthritis. Less frequently, nonseptic arthritis, hemarthrosis, and cellulitis at the injection site and surrounding tissues have been reported.” These are important facts that horse owners and veterinarians should be aware of. The lack of such risk information regarding Adequan® i.a. causes the drug to be misbranded within the meaning of sections 502(a) [21 U.S.C. 352(a)] and 201(n) [21 U.S.C. 321(n)] of the Act.

## Conclusion and Requested Action

As discussed above, the promotional labeling piece omits important risk information for Adequan® i.a., and promotes Adequan® i.m. and Adequan® i.a. for new intended uses that are not the subject of an approved NADA. Accordingly, the drugs are adulterated within the meaning of section 501(a)(5) [21 U.S.C. 351(a)(5)] and Adequan® i.a. is

misbranded within the meaning of sections 502(a) [21 U S C 352(n)] and 201(n) [21 U S C 321(n)] of the Act

The Division of Surveillance requests that Luitpold Animal Health immediately cease dissemination of the Adequan® promotional labeling piece described above, and all similar promotional items. Future promotional materials should adequately address risk information, and promote the drugs only for their approved intended uses. Please submit a written response within 30 days of receipt of this letter describing your intent to comply with this request. Please direct your response to Dr. Lynn Post at the Food and Drug Administration, Center for Veterinary Medicine, HFV-210, 7519 Standish Place, Rockville, MD 20855. We remind you that only written communications are official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to see that your promotional items for Adequan® comply with the requirements of the Act and its implementing regulations.

Sincerely yours,

Daniel G. McChesney, Ph.D.  
Director,  
Office of Surveillance and Compliance  
Center for Veterinary Medicine