DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 19 2013

FDA-2013-P-0632-0001/CP

Piedmont Animal Health
Attention: Kathleen G. Palma, Ph.D.
Vice President of Research, Development and Regulatory
204 Muirs Chapel Road, Suite 200
Greensboro, NC 27410

Re: Suitability Petition Request

Dear Dr. Palma:

We approve the suitability petition (FDA-2013-P-0632/CP1) you filed on behalf of Piedmont Animal Health on May 24, 2013. In the petition, you requested permission to submit an abbreviated new animal drug application (ANADA) for a proposed generic new animal drug that differs in dosage form from the reference listed new animal drug (RLNAD) and differs in the number of manufactured strengths. The proposed generic new animal drug is a deracoxib formed soft chewable tablet with the same indications and dosage schedule approved for the RLNAD, which is a compressed tablet.

The RLNAD is DERAMAXX (deracoxib) Chewable Tablets, sponsored by Novartis Animal Health US, Inc. under NADA 141-203. DERAMAXX is approved for the control of pain and inflammation associated with osteoarthritis, for the control of postoperative pain and inflammation associated with dental surgery, and for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs.

Your proposed change in dosage form from the RLNAD is a permissible change that can be considered through a suitability petition, as defined under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act. We are approving the petition because we find that the proposed change in dosage form does not require you to conduct investigations to show the safety and effectiveness of the generic new animal drug for its intended uses. Your proposed change to drop the 50 mg strength is not a change that is considered under a suitability petition. It will be addressed at the time of the ANADA submission.

Approval of this suitability petition does not guarantee approval of the ANADA for your proposed generic new animal drug. We will make that determination after you have submitted your ANADA for our review.

You did not cite the correct regulation for a categorical exclusion from the requirement to file an environmental assessment. The correct regulation to cite for this agency requested action is 21 CFR 25.15. You may use the following language:

> In accordance with 21 CFR 25.15, <**Sponsor name**> claims that the agency requested action in this suitability petition qualifies for categorical exclusion from the requirement to prepare an environmental assessment as set forth in 21 CFR

25.30(h). We confirm that to our knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21.

When you submit your ANADA, you must identify the RLNAD referred to in this suitability petition, and include a copy of this letter. We recommend that you request a pre-submission conference according to 21 CFR 514.5 to discuss the requirements and potential pathways for approval of the application.

A copy of this letter approving your petition will be placed on public display at www.regulations.gov with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. If you have any questions, please contact Dr. John K. Harshman, Director, Division of Generic Animal Drugs, at (240) 276-8197.

Sincerely,

Steven D. Vaughn, DVM

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine