DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 9 2013

FDA-2013-P-0996/CP1

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-0996) you filed on behalf of Piedmont Animal Health on August 13, 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). The proposed generic new animal drug is a cefpodoxime proxetil formed, soft chewable tablet with the same indications and dosage schedule approved for the RLNAD, which is a compressed tablet.

The RLNAD is SIMPLICEF (cefpodoxime proxetil) Tablets, sponsored by Zoetis Inc. under NADA 141-232. SIMPLICEF is approved for use in dogs for the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius, S. aureus, Streptococcus canis* (group G, β-hemolytic), *Escherichia coli, Pasteurella multocida,* and *Proteus mirabilis*.

Your proposed change 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 (the 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 proposed intended uses.

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.

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) 402-0866.

Sincerely,

for

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