DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 18 2013

FDA-2013-P-1101-0001/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: Request for approval of a suitability petition

Dear Dr. Palma:

We approve your suitability petition (FDA 2013-P-1101-0001/CP) dated May 22, 2013. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic clindamycin hydrochloride soft chewable tablet that differs in dosage form from the reference listed new animal drug (RLNAD). The RLNAD is ANTIROBE (clindamycin hydrochloride) Capsules, sponsored by Zoetis Inc. under NADA 120-161. ANTIROBE is approved for the treatment of infections in dogs caused by susceptible strains of the designated microorganisms in the specific conditions listed:

> Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*).
>
> Deep wounds and abscesses due to *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.
>
> Dental infections due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.
>
> Osteomyelitis due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

The proposed generic new animal drug is a soft chewable tablet containing 25 mg, 75 mg, 150 mg, or 300 mg clindamycin. The RLNAD is a capsule available in 25 mg, 75 mg, 150 mg, and 300 mg tablet strengths. The approved dosage schedule is dependent upon the indication. When treating wounds, abscesses, and dental infections, the dose is 2.5 to 15 mg per pound (lb) body weight every 12 hours for a maximum of 28 days. When treating osteomyelitis, the dose is 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

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. Therefore, we approve the petition under section 512(n)(3)(C) of the act.

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 for your proposed generic new animal drug, you must identify the reference listed new animal drug referred to in this suitability petition and include a copy of this letter. We recommend that you request a presubmission conference, according to 21 CFR 514.5, to discuss the requirements and potential pathways for approval of the application.

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.

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, D.V.M.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

cc: HFV-170 (Petition File)
HFA-305 (Division of Dockets Management)