



2013 MAY 24 A 10:27

May 22, 2013

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: ANADA Suitability Petition

Dear Dr. Harshman:

Enclosed please find a Suitability Petition submitted in accordance with section 512 (n)(3) of the Federal Food, Drug and Cosmetic Act on behalf of the sponsor, Piedmont Animal Health, 204 Muirs Chapel Road Suite 200, Greensboro, NC 27301, USA.

The Sponsor requests through this Suitability Petition permission to file an Abbreviated New Animal Drug Application (ANADA) for a generic new animal drug clindamycin hydrochloride soft chewable tablet which differs from the pioneer product, ANTIROBE®-clindamycin hydrochloride capsule approved under NADA 120-161 (Pharmacia and Upjohn Company, Division of Pfizer, Inc.), by the following characteristic: a capsule versus a soft chewable tablet. The generic product will be a soft chewable trapezoidal tablet, whereas the pioneer product is a capsule.

If you have any questions concerning this petition, please contact me at 336-708-2842.

Sincerely,

Kathleen G. Palma, Ph.D.
Vice President of Research, Development and Regulatory

FDA-2013-P-1101

2013-3877

CP

SUITABILITY PETITION

Identification of Petitioner:

Piedmont Animal Health
204 Muirs Chapel Road
Suite 200
Greensboro, NC 27410

Citation:

Piedmont Animal Health submits this petition under section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act.

Action Requested:

Piedmont Animal Health (PAH) requests permission from the Director to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form than the pioneer product.

Pioneer Product: ANTIROBE®-clindamycin hydrochloride capsules
Company: Pharmacia and Upjohn Company, Division of Pfizer, Inc.
NADA #: 120-161
Active Ingredient: clindamycin hydrochloride
Species: canine

The pioneer product is a capsule formulation. The proposed generic product will be a formed soft chewable tablet with a texture similar to semi-moist dog food. The amount of active ingredient will be the same for both pioneer and generic products. The method of administration (oral) will be the same for the proposed generic product as the parent product. A copy of pioneer labeling is enclosed.

Statement of Grounds:

The active ingredient in ANTIROBE® is clindamycin hydrochloride formulated as a capsule. The pioneer product is administered orally in dogs for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

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 melaninogenus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

The proposed generic product will have the same indications and dosage, be administered orally, have the same therapeutic effect and contain the same cautions and warnings as the pioneer product. The generic will differ in that the formulation of a capsule for the pioneer as compared to a formed soft chewable tablet for the generic product. The label will differ as it relates to the different companies manufacturing the two products, the trade name, and the difference between a capsule of the pioneer product and a soft chewable tablet of the generic product. The pioneer product states it is a capsule and the generic product will state it is a soft chewable tablet. The parts of the pioneer label and information for dog owners that will be different are underlined. Those underlined parts on pages 1-14 are attached.

Environmental Impact:

The action of submission and review of this Suitability Petition should not have an impact on the environment. Therefore, Piedmont Animal Health will request a categorical exclusion from the requirements to file an environmental assessment as provided under 21 CFR 25.24(a)(8).

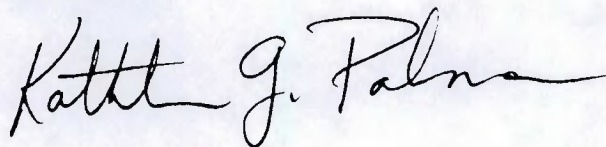
Economic Impact:

Piedmont Animal Health will provide an economic impact analysis if requested by the Division.

Certification:

Attached is a statement that Piedmont Animal Health has included all known unfavorable information regarding this Suitability Petition.

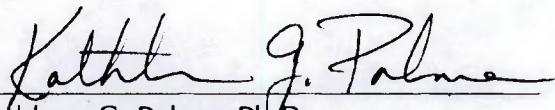
Sincerely,

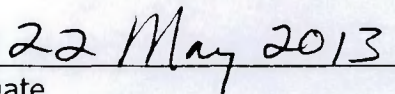
A handwritten signature in black ink, appearing to read 'Kathleen G. Palma'. The signature is fluid and cursive, with the first name 'Kathleen' being more prominent and the last name 'Palma' following in a similar style.

Kathleen G. Palma, Ph.D.
Vice President of Research and Development, Regulatory
Piedmont Animal Health

CERTIFICATION

The undersigned certifies that no unfavorable information related to this petition has been withheld from the attached Suitability Petition.


Kathleen G. Palma, Ph.D.


Date

Address: Piedmont Animal Health
 204 Muirs Chapel Road
 Suite 200
 Greensboro, NC 27410

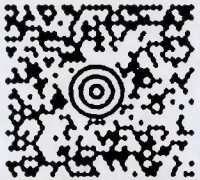
LISA APONTE WOLFF
336 544-0320 213
PIEDMONT PHARMACEUTICALS
204 MUIRS CHAPEL ROAD
GREENSBORO NC 27410

0.0 LBS LTR

1 OF 1

SHIP TO:

DOCKET'S MGMT BRANCH, HFA-305
336-544-0320
FOOD & DRUG ADMINISTRATION
ROOM 1061
5630 FISHERS LANE
ROCKVILLE MD 20857-0001



MD 207 9-83



UPS 2ND DAY AIR

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