



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 10, 2013

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

Dear Dr. Palma:

Your petition to the Food and Drug Administration requesting permission to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form than the pioneer product, was received by this office on 05/24/2013. It was assigned docket number FDA-2013-P-1101/CP1, and it was filed on 05/24/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Karen Kennard".

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)