



Food and Drug Administration Silver Spring MD 20993

March 10, 2020

John D. Franolic, Ph.D. Vice President of Regulatory Affairs Akorn Animal Health Inc 1925 West Field Court, Suite 300 Lake Forest, IL 60045

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to pursue approval of an Abbreviated New Animal Drug Application for Neomycin and Polymixin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment, USP, that differs from the RLNAD in dosage strength of the Polymixin component was received by this office on 03/10/2020.

It was assigned docket number FDA-2020-P-1074. 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,

Dynna Bigby Supervisory Administrative Proceedings Officer Division of Dockets Management FDA/Office of Operations (OO)