## DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Silver Spring MD 20993

November 2, 2020

Jing Yang, Ph.D. Associate Director BF Innovation, Inc. 3 Bioscience Park Drive Farmingdale, NY 11735

## Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to confirm that CUTIVATE (Fluticasone Propionate Ointment 0.005%), approved under New Drug Application (NDA) N019957, held by FOUGERA PHARMACEUTICALS INC, is not discontinued for safety and efficacy reason was received by this office on 11/02/2020.

It was assigned docket number FDA-2020-P-2146. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

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