



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

April, 2, 2021

Re: Docket No. FDA-2020-P-2146

Dear Dr. Yang:

This letter responds to your citizen petition received on November 2, 2020, requesting that the Food and Drug Administration (FDA) determine whether Cutivate (fluticasone propionate) ointment, 0.005%, was withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Cutivate (fluticasone propionate) ointment, 0.005%, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Cutivate (fluticasone propionate) ointment, 0.005%, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-3600.

Sincerely,

Heather A. Dorsey
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure