BF Innovation

BFREF: 2020FDACP001

Nov 02, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned, BF Innovation Inc., acting on behalf of Bright Future Pharmaceutical Laboratories Limited, respectfully submits this petition pursuant to 21 CFR 10.25 and 10.30, and in accordance with 21 CFR 314.122 and 314.161, requesting the FDA (Food and Drugs Administration) commissioner to confirm whether an Orange Book Listed discontinued Drug (CUTIVATE®), the Reference Listed Drug (RLD) of Fluticasone Propionate Ointment 0.005%, has been voluntarily withdrawn for the reasons other than safety or effectiveness.

A. Action Requested

The petitioner request the FDA commissioner 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.

B. Statement of Grounds

Under the FDC Act 505(j)(2), an ANDA must rely for safety and effectiveness on a Reference Listed Drug (RLD). As per 21 CFR 314.122 and 314.161, if a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness.

Also, as per 21 CFR 314.162, if FDA determines and withdraws a listed drug from sale for reasons of safety and efficacy, then the drug listing is removed from the Orange Book. However, if FDA determines that the listed drug was withdrawn from sale not for the reasons of safety and efficacy, then it remains listed in the Orange Book and may be cited in an ANDA as an RLD.

The Orange Book lists the CUTIVATE® (Fluticasone Propionate Ointment 0.005%), NDA N019957 as an RLD with the market-status as discontinued in the "Discontinued Drug Product List" section of the Orange Book. Currently, the Orange Book lists ANDA A076668 by

PERRIGO NEW YORK INC. as Reference Standard (RS) for Fluticasone Propionate Ointment 0.005%.

Based on above cited facts, it appears that CUTIVATE® (Fluticasone Propionate Ointment 0.005%) has been withdrawn from the market for reasons other than the safety and efficacy. Please confirm.

C. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR 25.31.

D. Economic Impact

In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. The Petitioner hereby commits to promptly provide this information, if so requested.

E. Certification

BF Innovation Inc. has certified that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner, which is unfavorable to the petition.

Respectfully submitted,

Jing Yang

Jing Yang Ph.D.

Associate Director

BF Innovation Inc.