DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

May 26, 2020

Robert J. Moccia
President and CEO
Encore Dermatology, Inc.
5 Great Valley Parkway, Suite 200
Malvern, PA 19355

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA take the following three actions described below:

1. Refuse to approve the Glenmark generic topical clobetasol propionate product submitted under ANDA 214191, and any similarly formulated generic products, because there is a reasonable basis to conclude that Glenmark made formulation changes, including significant changes to the vehicle, that likely increase absorption and raise unanswered questions of safety and effectiveness.

2. Require Glenmark and similarly situated generic applicants to submit their new formulations under a new drug application with adequate data demonstrating safety and effectiveness.

3. If FDA does allow Glenmark, and similarly situated generic applicants, to proceed with an ANDA, require Glenmark and others to:

    a. establish bioequivalence with a comparative clinical endpoint study; and

    b. support their ANDAs with (i) systemic exposure data, (ii) HPA axis suppression data, and (iii) local safety data to ensure that the proposed formulations have the same safety profile as Impoyz.

Your submission was received by this office on 05/22/2020 and it was assigned docket number FDA-2020-P-1421. 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 Gorham-Bigby
Digitally signed by Dynna Gorham-Bigby
Date: 2020.05.27 14:08:28 -04'00'

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