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

May 11, 2021

Re: Docket No. FDA-2020-P-2212

Dear Mr. Moccia:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on November 13, 2020. Your petition requests that the Agency:

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.

Alternatively, if the Agency does allow Glenmark, and similarly situated generic applicants, to proceed with an ANDA, your petition requests that the Agency require Glenmark and others to:

1. Establish bioequivalence with a comparative clinical endpoint study; and
2. 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.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research