NDA 207917/S-004 and S-008

SUPPLEMENT APPROVAL

Galderma Laboratories, LP
Attention: Randy Russell
Authorized Agent
14501 North Freeway
Fort Worth, TX 76177

Dear Mr. Russell:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 25, 2019 and January 12, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Epiduo Forte (adapalene and benzoyl peroxide) topical gel.

These Prior Approval sNDAs provide for:

- a Pregnancy and Lactation Labeling Rule (PLLR) conversion of the Prescribing Information (PI)
- an update to the post-marketing experience Section 6.2 of the PI
- an update to the Patient Package Insert (PPI)
- an update to the carton and container labels.

APPROVAL & LABELING

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

- Insert a space in the HIGHLIGHTS OF PRESCRIBING INFORMATION immediately prior to the WARNINGS AND PRECAUTIONS section.
- Insert a space between the title in the FULL PRESCRIBING INFORMATION and INDICATIONS AND USAGE section.
- In the PI, update the HIGHLIGHTS OF PRESCRIBING INFORMATION revised date to: 04/2022
- Update the Revised date in the PPI to 04/2022

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling for the PI and PPI, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted via email March 21, 2022, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 207917/S-004 and S-008**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, call H. F. Van Horn III, PharmD, MBA, Regulatory Project Manager, at (301) 837-7389.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TATIANA OUSSOVA
04/27/2022 02:04:39 PM