NDA 210566/S-002

SUPPLEMENT APPROVAL
Fulfillment of Postmarketing Commitment

Mayne Pharma LLC
Attention: Terri Nataline
Vice President, Regulatory Affairs
1240 Sugg Parkway
Greenville, NC 27834

Dear Ms. Nataline:

Please refer to your supplemental new drug application (sNDA) dated and received October 25, 2019, of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lexette® (halobetasol propionate) topical foam, 0.05%.

This Prior Approval supplemental new drug application provides for labeling update to include data from the vasoconstrictor assay (VCA) study conducted to fulfill Postmarketing Commitment 3344-2 as described in the Approval Letter dated May 24, 2018.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling, with minor editorial revisions listed below:

- Deletion of cross-references in Section 8.4

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 Prescribing Information, Patient Package Insert and Instructions for Use, 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING COMMITMENT

We have reviewed your submission and conclude that the below commitment was fulfilled:

3344-2 Conduct a single point vasoconstrictor assay with adequate bracketing using visual assessment to determine the topical corticosteroid classification of your commercial formulation.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

3344-1 Conduct a maximal use pharmacokinetic (PK) and HA axis suppression study in subjects 12 years to < 17 years of age with psoriasis.

The timetable contained in the May 24, 2018 Approval Letter, states that you will conduct this study according to the following schedule:

Study/Trial Completion: 02/2020
Final Report Submission: 06/2020

REPORTING REQUIREMENTS

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

[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 Qianyiren Song, Regulatory Project Manager, at 301-796-2581.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use

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
04/23/2020 05:20:45 PM