Dear Dr. Babilonia:

Please refer to your supplemental biologics license application (sBLA), dated and received November 26, 2019, and your amendments, submitted under section 351(a) of the Public Health Service Act for DUPIXENT (dupilumab) injection, for subcutaneous use.

This Prior Approval supplemental biologics application contains the final summary report for the following postmarketing requirement listed in the March 28, 2017 BLA approval letter and provides for a new patient population: patients with moderate-to-severe atopic dermatitis (AD) aged ≥ 6 to < 12 years.

3183-1 Conduct a randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of dupilumab administered concomitantly with topical therapy in subjects 6 years to less than 12 years of age with severe atopic dermatitis.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,¹ that is identical to the enclosed labeling (text for the Prescribing Information, [http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm)

Reference ID: 4613389
Patient Package Insert, and Instructions for Use) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

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.*

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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 REQUIREMENT(S)/COMMITMENT(S)**

We have reviewed your submission and conclude that postmarketing requirement 3183-1 was fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the March 28, 2017 approval letter that are still open.

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov. Information and Instructions for completing the form can be found at FDA.gov.

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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](https://www.fda.gov/RegulatoryInformation/Guidances/default.htm).

3 For the most recent version of a guidance, check the FDA guidance web page [https://www.fda.gov/media/128163/download](https://www.fda.gov/media/128163/download).


U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov
REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81). If you have any questions, call Matthew White, Senior Regulatory Project Manager, at 301-796-4997.

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
05/26/2020 10:43:01 AM