Dear Dr. Babilonia:

Please refer to your supplemental biologics license applications (sBLAs) BLA 761055/S-015, dated and received January 24, 2019, and BLA 761055/S-017, dated and received May 20, 2019, and your amendments, submitted under section 351(a) of the Public Health Service Act for DUPIXENT (dupilumab) injection, for subcutaneous use.

We acknowledge receipt of your major amendment to S-017 dated March 9, 2020, which extended the goal date for this supplement by three months.

Changes Being Effected supplemental biologics application S-015 provides for updating the label with information for patients and prescribers about an enrolling pregnancy exposure registry.

Prior Approval supplemental biologics application S-017 provides for a new 300 mg (150 mg/mL) pre-filled pen presentation.

**APPROVAL & LABELING**

We have completed our review of these applications, as amended. They are 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, [Wix](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm)

Reference ID: 4627686
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.²

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).

**CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and carton and container labeling submitted to S-017 on May 20, 2019, 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 BLA 761055/S-017.” Approval of this submission by FDA is not required before the labeling is used.

**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.³

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,

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

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov
accompanying a Form FDA 2253. Form FDA 2253 is available at FDA.gov.\textsuperscript{4} Information and Instructions for completing the form can be found at FDA.gov.\textsuperscript{5}

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\}

Kendall A. Marcus, MD
Director
Division of Dermatology and Dentistry
Office of Drug Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):

\begin{itemize}
  \item Content of Labeling
    \begin{itemize}
      \item Prescribing Information
      \item Patient Package Insert
      \item Instructions for Use
    \end{itemize}
  \item Carton and Container Labeling
\end{itemize}

\textsuperscript{4} \url{http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf}
\textsuperscript{5} \url{http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf}
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/
KENDALL A MARCUS
06/18/2020 05:11:02 PM