BLA 761059/S-004

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Samsung Bioepis Co., Ltd
c/o Cardinal Health 127, Inc.
7400 West 110th Street
Overland Park, Kansas 66210

Attention: Todd Phillips, PharmD, RAC
Director, Global Regulatory Affairs

Dear Dr. Phillips:

Please refer to your supplemental biologics license application (sBLA), dated and received August 17, 2021, and your amendments, submitted under section 351(k) of the Public Health Service Act for Hadlima (adalimumab-bwwd) injection 40 mg/0.8 mL.

This Prior Approval supplemental biologics license application provides for:

- Expansion of the indication of polyarticular Juvenile Idiopathic Arthritis (pJIA) to now include patients 2 years of age and older,
- Expansion of the indication of Crohn's Disease (CD) to now include patients 6 years of age and older,
- Introduction of a 40 mg/0.8 mL single-dose glass vial presentation for institutional use only,
- Introduction of Samsung Biologics Co. Ltd (SBL) (FEI 3010479596) as a drug product manufacturing site for the institutional use vial presentation and as a drug product quality control (QC) release (sterility and endotoxin) and in-process (all tests) testing site,
- Introduction of Sharp Corporation (FEI 3004161147) as a drug product secondary packaging site for the institutional use vial presentation.

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.

WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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, Instructions for Use, and Medication Guide) 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, 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 761059/S-004**." Approval of this submission by FDA is not required before the labeling is used.

[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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We have received your submission dated August 17, 2021, containing the final reports for the following postmarketing requirements listed in the July 23, 2019, approval letter for BLA 761059.

3671-1	Assessment of Hadlima (adalimumab-bwwd) for the treatment of polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients ages 2 to less than 4 years of age.
3671-2	Assessment of Hadlima (adalimumab-bwwd) for the treatment of Pediatric Crohn's Disease (CD) in pediatric patients 6 years to 17 years of age.
3671-3	Assessment of Hadlima (adalimumab-bwwd) for the treatment of pediatric ulcerative colitis (UC) in pediatric patients 5 years to 17 years of age.
3671-4	Develop a new presentation that can be used to accurately administer Hadlima (adalimumab-bwwd) to pediatric patients who weigh less than 30 kg.

We note that you have fulfilled the pediatric study(ies) requirement for all relevant pediatric age groups for this application.

We remind you that there are postmarketing commitments 3671-5, 3671-6, and 3671-7 listed in the July 23, 2019, 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.*[3]

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

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[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 Sadaf Nabavian, Regulatory Project Manager, at 301-796-2777.

Sincerely,

{See appended electronic signature page}

Nikolay P. Nikolov, MD
Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

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