

BLA 761059/S-018

SUPPLEMENT APPROVAL

Samsung Bioepis Co., Ltd.
c/o Cardinal Health
Attention: Brian Cudney
US Agent
7400 West 110th Street, Suite 150
Overland Park, KS 66210

Dear Brian Cudney:

Please refer to your supplemental biologics license application (sBLA), dated and received August 30, 2023, and your amendments, submitted under section 351(k) of the Public Health Service Act for Hadlima (adalimumab-bwvd) injection.

This Category F Prior Approval sBLA seeks licensure of Hadlima (adalimumab-bwvd) injection for subcutaneous use as interchangeable with US-licensed Humira (adalimumab) injection for subcutaneous use as follows:

- Hadlima 40 mg/0.8 mL in a prefilled syringe (PFS) as interchangeable with US-Humira 40 mg/0.8 mL in a PFS.
- Hadlima 40 mg/0.8 mL in a glass vial as interchangeable with US-Humira 40 mg/0.8 mL in a glass vial.

(b) (4)

Hadlima is licensed as biosimilar to US-licensed Humira for the following indications:

- Rheumatoid Arthritis (RA): reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA.
- Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.

- Psoriatic Arthritis (PsA): reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
- Ankylosing Spondylitis (AS): reducing signs and symptoms in adult patients with active AS.
- Crohn's Disease (CD): treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- Ulcerative Colitis (UC): treatment of moderately to severely active ulcerative colitis in adult patients.
- Plaque Psoriasis (Ps): treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
- Hidradenitis Suppurativa (HS): treatment of moderate to severe hidradenitis suppurativa in adult patients.
- Uveitis (UV): treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

For administrative purposes, we have split S-018 into the following supplements:

- BLA 761059/S-018 – Hadlima (adalimumab-bwvd) 40 mg/0.8 mL, in a PFS and glass vial.

[REDACTED] (b) (4)

The subject of this correspondence is BLA 761059/S-018. [REDACTED] (b) (4)

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).

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.

At this time, no pediatric studies will be required under PREA for your BLA.

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>.

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

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. 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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Saharat Patanavanich, Regulatory Project Manager, at (240) 402-0139 or Saharat.patanavanich@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Raj Nair, MD
Director (Acting)
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling

- Prescribing Information
- Medication Guide (revised July 2023)
- Instructions for Use (revised December 2022)

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

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <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/

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