BLA 761059/S-013

SUPPLEMENT APPROVAL

Samsung Bioepis Co., Ltd.; c/o Cardinal Health 127 Inc
Attention: Brian Cudney
Director, Chemistry, Manufacturing, and Controls
7400 West 110th St, Suite 150
Overland Park, KS 66210

Dear Mr. Cudney:

Please refer to your supplemental biologics license application (sBLA) dated and received October 27, 2022, and your amendments, submitted under section 351(k) of the Public Health Service Act for Hadlima (adalimumab-bwwd) injection.

This "Changes Being Effected" supplemental biologics license application proposes to include drug sample labeling for Hadlima (adalimumab-bwwd) 40 mg/0.4 mL in a single-dose autoinjector.

APPROVAL & LABELING

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

We note that your December 23, 2022, submission includes final printed labeling (FPL) for your prescribing information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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) 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format that includes the changes approved in this supplemental application.

CARTON AND CONTAINER LABELS

We acknowledge your February 2, 2023, submission containing your final drug sample container label and your February 16, 2023, submission containing your final drug sample printed carton label.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, email or call Shazma Aftab, PharmD, Regulatory Business Process Manager, at shazma.aftab@fda.hhs.gov or (301) 796 - 3138.

Sincerely,

{See appended electronic signature page}

Susan Kirshner, PhD
Division Director
Division of Biotechnology Review and Research III
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Carton and Container Labeling

Susan Kirshner

Digitally signed by Susan Kirshner
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