



BLA 761054/S-029

APPROVAL LETTER

Samsung Bioepis Co., Ltd.
c/o Cardinal Health Regulatory Sciences
Attention: Todd Phillips, PharmD, RAC
Director, Global Regulatory Affairs
7400 West 110th St.
Suite 300
Overland Park, KS 66210

Dear Dr. Phillips:

Please refer to your supplemental biologics license application (sBLA) dated and received September 27, 2021, and your amendments, submitted under section 351(k) of the Public Health Service Act for Renflexis (infliximab-abda) for injection.

This Prior Approval sBLA provides for changes to the product label to allow for storage of diluted Renflexis drug product (i.e., in-use) at room temperature at 25 °C (77°F) for up to 4 hours, including reconstitution and dilution time; or refrigerated at 2°C to 8°C (36°F to 46°F) for up to 34 days and an additional 6 hours at 25°C after removal from a refrigerator.

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.

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.gov¹, that is identical to the enclosed labeling (text for the prescribing information, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effectuated” (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 Effectuated” (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, 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).

This information will be included in your biologics license application file.

If you have any questions, please contact Nowrin Kakon, Regulatory Business Process Manager, at Nowrin.Kakon@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Cyrus Agarabi, Pharm.D. Ph.D., CAPT, USPHS
Acting Director
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling

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>.



Cyrus
Agarabi

Digitally signed by Cyrus Agarabi

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