BLA 761045/S-011

SUPPLEMENT APPROVAL

Sandoz Inc
Attention: Jackline George
Regulatory Affairs Manager, Biopharma
100 College Road West
Princeton, NJ 08540

Dear Ms. George:

Please refer to your supplemental Biologics License Application (sBLA) dated and received May 10, 2022, and your amendments, submitted under section 351(k) of the Public Health Service Act for Ziextenzo (pegfilgrastim-bmez) injection.

This Prior Approval sBLA provides for changes to the primary packaging material for the LA-EP2006 drug product from the currently used (b) (4) syringe with a 27 G x ½" needle and rubber needle shield (b) (4) to a (b) (4) syringe (b) (4) 29 G x ½" needle and a rubber needle shield (b) (4) for syringe glass barrels.

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 May 10, 2022, submission includes final printed labeling (FPL) for your prescribing information, patient package insert, and instructions for use. 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, text for the 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, 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

We acknowledge your September 1, 2022, submission containing final printed carton and container labeling.

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

If you have any questions, call Anika Lalmansingh, Senior Regulatory Business Process Manager, at (240) 402 - 0356.

Sincerely,

{See appended electronic signature page}

CAPT Cyrus Agarabi, Pharm.D., Ph.D.
United States Public Health Service
Director
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

[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.

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Cyrus Agarabi

Digitally signed by Cyrus Agarabi
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