BLA 761121/S-003

APPROVAL LETTER

Genentech Inc.
Attention: Lisa deCardenas
Regulatory Program Director
1 DNA Way
South San Francisco, CA 94080

Dear Ms. deCardenas:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received May 19, 2020, and your amendments, submitted under section 351(a) of the Public Health Service Act for Polivy (polatuzumab vedotin-piiq) for injection.

This Prior Approval sBLA provides for:

- Introduction of a new polatuzumab vedotin-piiq 30 mg/vial lyophilized drug product configuration manufactured at the Roche Parenteral Production Facility, Kaiseraugst, Switzerland (PKau),
- Transfer of release and stability analytical procedures to PKau,
- Addition of identity release testing by Peptide Map,
- Addition of moisture release testing by Near-Infrared Spectrometry, as an alternative method to moisture determination by the Karl Fischer method,
- Addition of Roche Diagnostics, GmbH, Mannheim, Germany as a labeling and secondary packaging site,
- Extension of the storage duration after dilution in 0.9% Sodium Chloride from 24 hours to 36 hours at 2°C to 8°C,

(b) (4)

APPROVAL & LABELING

We have completed our review of this supplemental application, 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.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 *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

Submit final printed carton and container labeling that are identical to enclosed carton and container labeling and carton and container labeling submitted on May 19, 2020, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 "**Product Correspondence – Final Printed Carton and Container Labeling for approved BLA 761121/S-003.**" Approval of this submission by FDA is not required before the labeling is used.

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

If you have any questions, call Anita Brown, Regulatory Business Process Manager, at Anita.Brown@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gibbes Johnson, Ph.D.
Director
Division of Biotechnology Review and Research IV
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.
[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

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

Gibbes Johnson

Digitally signed by Gibbes Johnson
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