BLA 125554/S-103

APPROVAL LETTER

Bristol Myers Squibb Company
Attention: Noemi Guma, PhD
Director - US Regulatory Lead, Global Regulatory Strategy & Policy
P.O. Box 5326
Princeton, NJ 08543-5326

Dear Dr. Guma:

Please refer to your supplemental biologics license application (sBLA) dated and received April 30, 2021, submitted under section 351(a) of the Public Health Service Act for Opdivo (nivolumab) injection.

This Prior Approval sBLA provides for the addition of the Nivolumab Injection, 120 mg/12 mL (10 mg/mL) vial presentation, which will be manufactured at Vetter Pharma-Fertigung GmbH & Co. KG, Germany.

APPROVAL & LABELING

We have completed our review of this sBLA. 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 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, 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 carton and container labeling submitted on April 30, 2021, 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 125554/S-103.**" 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 Kelly Ballard, Senior Regulatory Business Process Manager, at (301) 348 - 3054.

Sincerely,

{See appended electronic signature page}

Emily Jing, Ph.D.
On behalf of
David Frucht, M.D.
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

Xianghong Jing

Digitally signed by Xianghong Jing
Date: 8/27/2021 09:28:36AM
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