BLA 761069/S-016

APPROVAL LETTER

AstraZeneca UK Limited
Attention: Jamie Gillette, MS, RAC
Director, Global Regulatory Affairs
One Medimmune Way
Gaithersburg, MD 20878

Dear Ms. Gillette:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received May 20, 2019, and your amendments, submitted under section 351(a) of the Public Health Service Act for Imfinzi (durvalumab) injection.

This Prior Approval supplemental biologics license application provides for the extension of in-use time at room temperature.

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 text. The extension of in-use time is approved at room temperature to 8 hours.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, 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.

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}

Patricia Hughes, Ph.D.
Branch Chief
Division of Microbiology Assessment
Office of Process and Facilities
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling

Patricia
Hughes Troost

Digitally signed by Patricia Hughes Troost
Date: 8/26/2019 12:20:40PM
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