DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 761049/S-002

CBE LABELING SUPPLEMENT – ACKNOWLEDGEMENT/APPROVAL

EMD Serono, Inc.
Attention: Rosann Reinhart
Head of U.S. Marketed Products Life Cycle Management & Compliance
Global Regulatory Affairs
1 Technology Place
Rockland, MA 02370

Dear Ms. Reinhart:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received August 10, 2017, submitted under section 351(a) of the Public Health Service Act for Bavencio (avelumab) Injection, for intravenous use, 20 mg/mL.

We also refer to our October, 12, 2017, supplement approval letter which inadvertently did not include, as an attachment, the Content of Labeling enclosure. Therefore, we are issuing this replacement letter with the approved labeling attached.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain October 12, 2017, the date of the original approval letter.

BLA SUPPLEMENT NUMBER: 761049/S-002

PRODUCT NAME: Bavencio (avelumab) Injection, for intravenous use, 20 mg/mL

DATE OF SUBMISSION: August 10, 2017

DATE OF RECEIPT: August 10, 2017

Because of the importance of the proposed changes, we accepted this supplement as a "Changes Being Effected" supplement under 601.12(f)(2)(i)(E).

This supplemental application, submitted as a “Special Labeling Supplement – Changes Being Effected” as described under 21 CFR 601.12(f)(2), provides for the following corrections to the

package insert: the addition of the term "rate" in reference to tumor response, in the Indications and Usage section of both the Highlights and Full Prescribing Information.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the prescribing information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).
As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the prescribing information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have questions, call Idara Udoh, Senior Regulatory Health Project Manager, at (301) 796-3074.

Sincerely,

{See appended electronic signature page}

Jeffrey Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFERY L SUMMERS
10/12/2017