



BLA 125377/S-84

## SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company  
Attention: Kruti Patel, R.Ph.  
Associate Director  
Global Regulatory Affairs, Safety and Biometrics-US Oncology  
P.O. Box 4000  
Princeton, NJ 08543-4000

Dear Ms. Patel:

Please refer to your Supplemental Biologics License Application (sBLA), dated September 2, 2016, submitted under section 351(a) of the Public Health Service Act for Yervoy (ipilimumab) injection, for intravenous use, 5 mg/mL.

This Prior Approval supplemental biologics application provides updates to the Use in Specific Populations, Pregnancy subsection, The Patient Counseling Information, Embryo-Fetal Toxicity subsection and the Medication Guide with Pregnancy Safety Surveillance Study information.

### **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.

### **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 the 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 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.

### **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 any questions, call Gina Davis, Senior Regulatory Health Project Manager, at (301) 796-0704.

Sincerely,

*{See appended electronic signature page}*

Jeffery Summers, MD  
Deputy Director for Safety  
Division of Oncology Products 2  
Office of Hematology and Oncology Products  
Center for Drugs Evaluation and Research

ENCLOSURE:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOSEPH E GOOTENBERG on behalf of JEFFERY L SUMMERS  
03/03/2017