DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125377/16

SUPPLEMENT BLA APPROVAL
February 16, 2012

Bristol-Myers Squibb Company
Attention: Cynthia Wojtaszek
Associate Director
Global Regulatory Sciences-US Oncology
Route 206 and Province Line Road
Princeton, NJ 08453

Dear Ms. Wojtaszek:

Please refer to your Supplemental Biologics License Application (sBLA), dated October 31, 2011, and received October 31, 2011, submitted under section 351 of the Public Health Service Act for YERVOY (ipilimumab).

We acknowledge receipt of your amendments dated November 29, 2011, January 13, 2012, and February 14, 2012, and your risk evaluation and mitigation strategy (REMS) assessment dated November 29, 2011.

This supplemental biologics license application provides for a proposed modification to the approved REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for YERVOY was originally approved on March 25, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of the creation of a limited-field, editable PDF form version of the "Yervoy Nursing Immune-Mediated Adverse Reaction Checklist."

Your proposed modified REMS, submitted on February 14, 2012, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on March 25, 2011.

There are no changes to the REMS assessment plan described in our March 25, 2011 letter.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

BLA 125377 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

BLA 125377 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125377
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA 125377
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

If you have any questions, call Erik S. Laughner, M.S., RAC (US), Senior Regulatory Health Project Manager, at (301) 796-1393.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
REMS
REMS Materials

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
02/16/2012