



BLA 125377/S-138

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING
COMMITMENTS**

Bristol-Myers Squibb Company
Attention: Jessica Zhu, PharmD
Senior Manager, Oncology, US Regulatory Lead
PO Box 5326
Princeton, NJ 08543

Dear Dr. Zhu:

Please refer to your supplemental biologics license application (sBLA) received May 29, 2026, submitted under section 351(a) of the Public Health Service Act for Yervoy (ipilimumab) injection.

This Prior Approval sBLA updates the Yervoy (ipilimumab) Prescribing Information (PI), specifically Section 1 INDICATIONS AND USAGE and Section 2 DOSAGE AND ADMINISTRATION, based on the August 15, 2025, Companion Diagnostic authorizations in support of PMCs 3450-3 and 3450-4.

APPROVAL & LABELING

We have completed our review of this application, as amended. 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 (Prescribing Information and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Information on submitting SPL files using eLIST may be found in 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(s), 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).

FULFILLMENT OF POSTMARKETING COMMITMENTS

We have received your submission dated September 15, 2025, and May 29, 2026, reporting on the following postmarketing commitments listed in the July 10, 2018, approval letter for BLA 125377/S-096.

- 3450-3 Commitment to support the availability through an appropriate analytical and clinical validation study using clinical trial data that will support labeling of an immunohistochemistry-based in vitro diagnostic device that is essential to the safe and effective use of ipilimumab for patients with tumors that are mismatch repair deficient.
- 3450-4 Commitment to support the availability through an appropriate analytical and clinical validation study using clinical trial data that will support labeling of a nucleic acid based in vitro diagnostic device that is essential to the safe and effective use of ipilimumab for patients with tumors that are microsatellite instability-high.

We have reviewed your submission and conclude that the above commitments were fulfilled.

This closes all of your postmarketing requirements and postmarketing commitments acknowledged in our July 10, 2018, letter. You are not required to report on the status of closed (released or fulfilled) PMRs/PMC in your annual report required under 21 CFR 601.70.

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>.

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 Amy Allen, Senior Regulatory Health Project Manager, at (301) 796-8416.

Sincerely,

{See appended electronic signature page}

Steven Lemery, M.D., M.H.S.
Director
Division of Oncology 3
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

STEVEN J LEMERY
06/12/2026 08:27:03 AM