BLA 761467/S-015

SUPPLEMENT APPROVAL

Merck Sharp and Dohme LLC
Attention: Janice Kim, PharmD, MS
Director, Global Regulatory Affairs
126 East Lincoln Avenue, P.O. Box 2000
RY34-A2014
Rahway, NJ 07065-0900

Dear Dr. Kim:

Please refer to your supplemental biologics license application (sBLA) dated and received March 26, 2026, and your amendments, submitted under section 351(a) of the Public Health Service Act for Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph) injection.

This Prior Approval supplemental biologics license application provides for updating the Keytruda Qlex label with an increased storage time of 96 hours at refrigerated temperature (2-8°C), with protection from light.

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, 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 guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*

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).

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 supplement 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, contact Dana T. Valentine, Pharm.D, RAC-Drugs, Regulatory Business Process Manager, at Dana.Valentine@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, Ph.D.
Director
Division of Product Quality Assessment XIII
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

- Content of Labeling
  - Prescribing Information

Patrick Lynch

Digitally signed by Patrick Lynch
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