



NDA 214876/S-006

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING COMMITMENT**

GlaxoSmithKline LLC (GSK)  
Attention: Alexandra Polacheck, PhD  
Director, Global Regulatory Affairs  
410 Blackwall Street  
Durham, NC 27701

Dear Dr. Polacheck:

Please refer to your supplemental new drug application (sNDA) dated October 7, 2025, received October 7, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zejula (niraparib) tablets.

This Prior Approval sNDA provides for updates to the Recent Major Changes section of Highlights and the Indications and Usage (1), Dosage and Administration (2) and Clinical Studies (14) sections of the Full Prescribing Information to reflect approval of a companion diagnostic for the maintenance HRD-positive ovarian cancer indication.

**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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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

<sup>2</sup> 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>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] 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 (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

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

### **FULFILLMENT OF POSTMARKETING COMMITMENT**

We have received your submission dated October 7, 2025, containing the final report for the following postmarketing commitment listed in the June 18, 2025, approval letter.

- 4865-1 Conduct an appropriate clinical validation study using clinical trial data to support the availability of an in vitro diagnostic device that is essential for the safe and effective use of niraparib for adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
- a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.

We have reviewed your submission and conclude that the above commitment was fulfilled.

This closes all of your postmarketing requirements and postmarketing commitments acknowledged in our June 18, 2025, 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 314.81(b)(2)(vii).

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov. Information and Instructions for completing the form can be found at FDA.gov.

### **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Ja'Kaya Wilson, Regulatory Project Manager, at [Jakaya.Wilson@fda.hhs.gov](mailto:Jakaya.Wilson@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Laleh Amiri-Kordestani, MD  
Director  
Division of Oncology 1  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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**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.**  
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/s/  
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CHRISTY L OSGOOD  
03/27/2026 02:14:15 PM  
Signing on Behalf of Laleh Amiri Kordestani