LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.
700 THIRTEENTH STREET, N.W.
SUITE 1200
KURT R. KARST WASHINGTON, D.C. 20005-5929 Direct Dial (202) 737-7544
(202) 737-5600 KKarst@hpm.com
FACSIMILE
(202) 737-9329
www.hpm.com

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SUBMITTED VIA REGULATIONS.GOV

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir/Madam:

The undersigned, on behalf of a client, submits this Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. § 314.93 and 21 C.F.R. §§ 10.20 and 10.30, to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") declare that the drug products Olaparib Tablets, 200 mg and 300 mg, are suitable for consideration in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The petitioner requests that FDA declare that Olaparib Tablets, 200 mg and 300 mg, are suitable for submission as an ANDA. As designated in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), the Reference Listed Drug ("RLD") upon which this petition is based is AstraZeneca Pharmaceuticals LP's LYNPARZA (olaparib) Tablets, which was approved for prescription use under New Drug Application ("NDA") 208558 in 100 mg and 150 mg strengths. The petitioner seeks to introduce new 200 mg and 300 mg tablet dosage form strengths for prescription use.

B. Statement of Grounds

FDC Act § 505(j)(2)(A)(iii) provides for the submission of an ANDA for a drug product that differs in strength from that of the listed drug provided FDA has first approved a petition permitting the submission of such an application.

LYNPARZA, a poly (ADP-ribose) polymerase inhibitor approved under NDA 208558 for the treatment of ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer, contains either 100 mg or 150 mg of olaparib in a tablet dosage form. A copy of the current Orange Book entry for LYNPARZA Tablets, 100 mg and 150 mg (NDA 208558), is included in ***Attachment 1***. The proposed drug products also contain olaparib in a tablet dosage form, but in 200 mg and 300 mg strengths. The petition is thus seeking a change in tablet strength to 200 mg and 300 mg from that of the RLD (100 mg and 150 mg).

The proposed changes in strength are consistent with the dosing recommendations of the RLD's approved labeling. *See* Prescribing Information, LYNPARZA Tablets, 100 mg and 150 mg, Dosage and Administration (Nov. 2023), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208558s028lbl.pdf (***Attachment 2***). ***First***, as shown in the table below, the recommended dosage of LYNPARZA Tablets is 300 mg taken orally twice daily, with or without food. The LYNPARZA Tablets Prescribing Information provides for the recommended dose of two 150 mg tablets administered twice daily. The proposed Olaparib Tablets, 300 mg, drug product would allow for the same recommended twice daily dose of Olaparib (*i.e.*, 300 mg), but administered in one 300 mg tablet of instead of two 150 mg tablets. Thus, the proposed 300 mg drug product would make an alternate tablet strength available for individuals who might benefit from a reduced tablet burden.

Second, to manage adverse reactions, the LYNPARZA Tablets Prescribing Information recommends considering interruption of treatment or dose reduction, as shown in the table below. The recommended dose reduction is 250 mg taken twice daily. If a further dose reduction is required, then a patient should reduce to 200 mg taken twice daily. The dose of 200 mg is given as two 100 mg tablets but administered in one 200 mg tablet of instead of two 100 mg tablets. Thus, the proposed 200 mg drug product would make an alternate tablet strength available for individuals who might benefit from a reduced tablet burden.

Labeling Details of Current and Proposed Olaparib Tablets Strengths

Product	Recommended dose	Dose modification for adverse events		Moderate Renal Impairment
		Initial reduction	Further reduction	
LYNPARZA Tablets: 100 mg & 150 mg	300 mg twice daily as two tablets of 150mg twice daily	250 mg twice daily as one tablet of 150 mg and one tablet of 100 mg	200 mg twice daily as two tablets of 100 mg twice daily	200mg twice daily as two tablets of 100 mg twice daily
Proposed Olaparib Tablets 200 mg & 300 mg	300 mg twice daily as one tablet of 300 mg twice daily		200 mg twice daily as one tablet of 200 mg twice daily	200 mg twice daily as one tablet of 200 mg twice daily

The proposed changes in strength from that of the RLD do not raise questions of safety or efficacy for the proposed drug products. Therefore, FDA should conclude that clinical investigations are not necessary to demonstrate safety or effectiveness of the proposed drug products.

There are no proposed changes in labeling with the exception of changes in strength sought in this petition. The uses, indications, warnings, and directions for use will remain the same as that of the RLD. Approved labeling for LYNPARZA Tablets, 100 mg and 150 mg (NDA 208558) is included as ***Attachment 2***. Draft labeling for the proposed drug products is included as ***Attachment 3***. Therefore, the Petitioner requests that FDA find that a change in tablet strength from 100 mg and 150 mg to 200 mg and 300 mg of olaparib raises no questions of safety or effectiveness.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FDC Act by requiring certain applications for a drug submitted under FDC Act § 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. *See* FDC Act § 505B(a)(1)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. *See id.* ANDAs submitted under an approved suitability petition for a change in strength are not subject to PREA requirements. *See* FDA, Draft Guidance for Industry, Pediatric Drug Development: Regulatory Considerations—Complying With the Pediatric Research Equity Act and Qualifying for Pediatric Exclusivity Under the Best Pharmaceuticals for Children Act, at 9 (May 2023). Petitioner asserts that PREA is not applicable to the proposed Olaparib Tablets, 200 mg and 300 mg, drug products because the proposed

changes concern only new strengths. As such, PREA should not serve as an impediment to the Agency granting this petition.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Sincerely,

Kurt R. Karst

KRK/eam
Attachments