

ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place both in-person and using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-06314 Filed 3-25-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2023-N-3168; FDA-2023-N-2780; FDA-2023-N-0940; and FDA-2023-N-3490]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601

Landsdown St., North Bethesda, MD 20852, 301-796-8867, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Extralabel Drug Use in Animals	0910-0325	2/28/2027
Premarket Notification for a New Dietary Ingredient	0910-0330	2/28/2027
Food and Drug Administration Rapid Response Surveys	0910-0500	2/28/2027
Application for Participation in Food and Drug Administration Fellowship Programs	0910-0780	2/28/2027

Dated: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1077]

AstraZeneca Pharmaceuticals LP; Withdrawal of Approval of New Drug Application for LYNPARZA (Olaparib) Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) for LYNPARZA (olaparib) Capsules, 50 milligrams (mg) held by AstraZeneca Pharmaceuticals LP (AZ), 1800 Concord Pike, Wilmington, DE 19803. AZ has voluntarily requested that FDA withdraw approval of this application

and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of March 26, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On December 19, 2014, FDA approved NDA 206162 for LYNPARZA (olaparib) Capsules, 50 mg, as monotherapy in patients with deleterious or suspected deleterious germline BRCA-mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. On July 14, 2022, FDA met with AZ to discuss the final overall survival (OS) results from the clinical trial entitled “A Phase III, Open Label, Randomised, Controlled, Multi-Centre Study to Assess the Efficacy and Safety of Olaparib Monotherapy Versus Physician’s Choice Single Agent Chemotherapy in the Treatment of Platinum Sensitive Relapsed Ovarian

Cancer in Patients Carrying Germline BRCA1/2 Mutations” (SOLO3).¹ The results indicated that patients who were taking olaparib potentially had a shorter OS than patients not on olaparib, particularly in the subgroup analysis of patients who had received three or more lines of chemotherapy. On July 26, 2022, the Agency asked AZ, in writing, to voluntarily permit FDA to withdraw approval of NDA 206162, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waive its opportunity for a hearing for NDA 206162. On January 19, 2023, AZ submitted a letter requesting withdrawal of approval of the application for LYNPARZA (olaparib) Capsules (NDA 206162) pursuant to § 314.150(d) and waiving its opportunity for a hearing.

Approval of NDA 206162 for LYNPARZA (olaparib) Capsules, and all amendments and supplements thereto, is also withdrawn under § 314.150(d) as

¹ The study, under its abbreviated title “Olaparib Treatment in Relapsed Germline Breast Cancer Susceptibility Gene (BRCA) Mutated Ovarian Cancer Patients Who Have Progressed at Least 6 Months After Last Platinum Treatment and Have Received at Least 2 Prior Platinum Treatments (SOLO3),” is available on the NIH National Library of Medicine’s ClinicalTrials.gov web page at <https://clinicaltrials.gov/ct2/show/NCT02282020>.