voluntarily permit FDA to withdraw approval of the indication for the treatment of adult patients with deleterious germline BRCA mutation-associated advanced ovarian cancer who have been treated with three or more chemotherapies, pursuant to § 314.150(d) and waive its opportunity for a hearing for NDA 208558. On August 19, 2022, AZ submitted a letter requesting withdrawal of approval of this indication for LYNPARZA (olaparib) Tablets (NDA 208558) pursuant to § 314.150(d) and waiving its opportunity for a hearing.

B. Withdrawal of Approval of Indication for Lynparza Tablets

Therefore, under § 314.150(d), approval of the indication for the treatment of adult patients with deleterious germline BRCA mutation-associated advanced ovarian cancer who have been treated with three or more chemotherapies for LYNPARZA (olaparib) Tablets is withdrawn as of March 26, 2024. Withdrawal of approval of this indication does not affect any other approved indication for LYNPARZA (200laparib) Tablets.

III. ZEJULA (Niraparib) Capsules

A. Application Background

On October 23, 2019, FDA approved NDA 208447 for ZEJULA (niraparib) Capsules, EQ 100 mg base, for the treatment of adult patients with advanced ovarian cancer (see table for full indication). On August 4, 2022, FDA met with GSK to discuss the status of the ZEJULA (niraparib) Capsules indication for the treatment of adult patients with advanced ovarian cancer. FDA requested that GSK voluntarily permit FDA to withdraw approval of this indication because the results from randomized trials of rucaparib and olaparib in similar treatment settings showed OS may be reduced in patients receiving PARP inhibitors. FDA stated that these results from two independent trials were concerning and suggested a class-wide effect for PARP inhibitors. In correspondence dated August 24, 2022, GSK acknowledged that because of the uncontrolled nature of the trial entitled ''A Phase 2, Open-Label, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Patients With Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received Three or Four Previous Chemotherapy Regimens'' [4] on which approval of this indication was based, it would be difficult to demonstrate that niraparib does not impact survival in this treatment setting. Therefore, GSK agreed to voluntarily withdraw the advanced ovarian cancer indication. On September 7, 2022, GSK submitted a letter requesting withdrawal of approval of this indication for ZEJULA (niraparib) Capsules pursuant to § 314.150(d) and waiving its opportunity for a hearing.

B. Withdrawal of Approval of Indication for Zejula Capsules

Therefore, under § 314.150(d), approval of the indication for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with HRD positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy for ZEJULA (niraparib) Capsules is withdrawn as of March 26, 2024. Withdrawal of approval of this indication does not affect any other approved indication for ZEJULA (niraparib) Capsules.

Dated: March 19, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06299 Filed 3–25–24; 8:45 am]

BILLING CODE 4164–01–P

[4] The study, under its abbreviated title ''A Study of Niraparib in Patients With Ovarian Cancer Who Have Received Three or Four Previous Chemotherapy Regimens (QUADRA),'' is available on the NIH National Library of Medicine's ClinicalTrials.gov web page at *https://clinicaltrials.gov/ct2/show/NCT02354586.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1179]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Use of Minimal Residual Disease as an Endpoint in Multiple Myeloma Clinical Trials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on April 12, 2024, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: FDA and invited participants may attend the meeting at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will have the option to participate via an online teleconferencing and/or video conferencing platform, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–1179. The docket will close on April 11, 2024. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end April 11, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before April 3, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–1179 for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Use of Minimal Residual Disease as an Endpoint in Multiple Myeloma Clinical Trials.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–2507, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss the use of minimal residual disease (MRD) as an endpoint in multiple myeloma clinical trials, including considerations regarding timing of assessment, patient populations, and trial design for future studies that intend to use MRD to support accelerated approval of a new product or a new indication.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials for online participants in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before April 3, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. Eastern Time and will take place entirely through an online meeting platform. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 1, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 2, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Takyiah Stevenson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/*

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]

BILLING CODE 4164–01–P

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.

[FR Doc. 2024–06265 Filed 3–25–24; 8:45 am]

BILLING CODE 4164–01–P

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.*