followup Report to Congress. The authority for us to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by SLTT governments as well as private sector partners. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA–NAFDS requires HHS and USDA, in coordination with DHS, to work together with SLTT to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The NAFDS charts a direction for how Federal agencies, in cooperation with SLTT governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (*i.e.,* 2019, 2023, 2027, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

FDA is the agency primarily responsible for obtaining the information from Federal and SLTT partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or SLTT agencies have completed (or are planning on completing) from 2024 to 2028. Planning for the local, territorial, and tribal information collections will commence during this period of renewal. The survey will continue to be repeated approximately every 2 to 4 years, as described in section 108 of FSMA. The NAFDS survey is being administered for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy is employed, such that the government agencies participating in food and agricultural defense are asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction are identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the *FDA.gov* web portal, and results will be analyzed by the interagency working group.

Description of Respondents: Respondents to this collection are SLTT government representatives (survey respondents) who are food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdictions.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SLTT Surveys	500	1	500	0.33 (20 minutes)	165

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The FDA Office of Partnerships reviewed the questionnaire and provided the estimate of time to complete the survey. The total burden is based on our previous experiences conducting surveys. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06316 Filed 3–25–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1056]

Clovis Oncology, Inc., AstraZeneca Pharmaceuticals LP, and GlaxoSmithKline LLC; Withdrawal of Approval of the Indications for Advanced Ovarian Cancer for Poly (ADP-Ribose) Polymerase Inhibitors RUBRACA (Rucaparib) Tablets, LYNPARZA (Olaparib) Tablets, and ZEJULA (Niraparib) Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the indications for the treatment of adult patients with advanced ovarian cancer for poly (ADP-ribose) polymerase (PARP) inhibitors under three new drug applications (NDAs) from multiple applicants. The applicants Clovis Oncology, Inc. (Clovis), AstraZeneca Pharmaceuticals LP (AZ), and GlaxoSmithKline, LLC (GSK) have each voluntarily requested that the Agency withdraw approval of the indications for the treatment of adult patients with advanced ovarian cancer for their respective PARP inhibitors and waived their opportunities for hearings. Applicant and indication details are further discussed in **SUPPLEMENTARY INFORMATION**.

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: The PARP inhibitors and their respective applicants, NDA numbers, and indications being withdrawn are included in the following table.

Application No.	Drug	Applicant	Indication being withdrawn
NDA 209115	Rubraca (rucaparib) Tablets, equivalent to (EQ) 200 milligrams (mg) base, EQ 250 mg base, and EQ 300 mg base.	Clovis Oncology, Inc., 5500 Flatiron Pkwy., Boulder, CO 80301.	for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.
NDA 208558	Lynparza (197laparib) Tablets, 100 mg and 150 mg.	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.	for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.
NDA 208447	Zejula (niraparib) Capsules, EQ 100 mg base.	GlaxoSmithKline, LLC, 2929 Walnut St., Suite 1700, Philadelphia, PA 19104.	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 homologous recombination deficiency (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. Select patients for therapy based on an FDA-approved companion diagnostic device for ZEJULA.

I. RUBRACA (Rucaparib) Tablets

A. Application Background

On December 19, 2016, FDA approved NDA 209115 for RUBRACA (rucaparib) Tablets, EQ 200 mg base, EQ 250 mg base, and EQ 300 mg base, for the treatment of adult patients with advanced ovarian cancer (see table for full indication [1]). On May 4, 2022, FDA met with Clovis to discuss the final results from the clinical trial entitled ''ARIEL4 (Assessment of Rucaparib in Ovarian CancEr TriaL): A Phase 3 Multicenter, Randomized Study of Rucaparib Versus Chemotherapy in Patients With Relapsed, BRCA Mutant, High Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.'' [2] The results indicated that patients in the intent-to-treat population who were taking rucaparib potentially had a shorter overall survival (OS) than patients not on rucaparib. At that meeting FDA conveyed that these results constituted a serious risk for patients receiving treatment with rucaparib. On May 10, 2022, the Agency asked Clovis, in writing, to voluntarily permit FDA to withdraw approval of the indication for the treatment of adult patients with deleterious BRCA mutation-associated epithelial ovarian, fallopian tube or primary peritoneal cancer who have been treated with two or more chemotherapies, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waive its opportunity for a hearing. On June 1, 2022, Clovis submitted a letter requesting withdrawal of approval of this indication for RUBRACA (rucaparib) Tablets pursuant to § 314.150(d) and waiving its opportunity for a hearing.

B. Withdrawal of Approval of Indication for RUBRACA Tablets

Therefore, under § 314.150(d), approval of the indication for the treatment of adult patients with deleterious BRCA mutation-associated epithelial ovarian, fallopian tube or primary peritoneal cancer who have been treated with two or more chemotherapies for RUBRACA (rucaparib) Tablets is withdrawn as of March 26, 2024. Withdrawal of approval of this indication does not affect any other approved indication for RUBRACA (rucaparib) Tablets.

II. LYNPARZA (Olaparib) Tablets

A. Application Background

On August 17, 2017, FDA approved NDA 208558 for LYNPARZA (olaparib) Tablets, 100 mg and 150 mg, for the treatment of adult patients with advanced ovarian cancer (see table for full indication). On July 14, 2022, FDA met with AZ to discuss the final 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).[3] 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

[1] The initially approved indication was ''as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic)-associated *advanced ovarian cancers* [emphasis added] who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.'' On April 6, 2018, the Agency approved a revised indication that, among other things, clarified the indication by listing the following specific advanced ovarian cancers in the indication: epithelial ovarian, fallopian tube, and primary peritoneal cancer.

[2] The study, under its abbreviated title ''ARIEL4: A Study of Rucaparib Versus Chemotherapy BRCA Mutant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Patients,'' is available on the National Institutes of Health (NIH) National Library of Medicine's ClinicalTrials.gov web page at *https://clinicaltrials.gov/ct2/show/NCT02855944.*

[3] 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.*

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