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.*

of March 26, 2024. Distribution of LYNPARZA (olaparib) Capsules, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06298 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–1221]

Electronic Submissions: Data Standards; Support and Requirement for the Clinical Data Interchange Standards Consortium Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule Version 1.0

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing support for the Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule Version 1.0 (SENDIG–AR v1.0) on March 26, 2024, and this standard will be required in submissions to CBER for studies that start after March 15, 2027. The Agency will update the FDA Data Standards Catalog (Catalog) to reflect this change.

DATES: Support for version CDISC SENDIG–AR v1.0 begins March 26, 2024. The requirement for electronic submissions using CDISC SENDIG–AR v1.0 begins for studies that start after March 15, 2027, for new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs). Submit either electronic or written comments at any time.

ADDRESSES: 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–1221 for ''Data Standards; Support and Requirement Begins for the Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule Version 1.0 (SENDIG–AR v1.0).'' Received comments 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.'' The Agency 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 to 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 this 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: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA's CBER is issuing this **Federal Register** notice to announce the date that support and requirement begins for CDISC SENDIG–AR v1.0. The guidance for industry entitled ''Providing Regulatory Submissions In Electronic Format—Standardized Study Data,'' published June 2021 (eStudy Data guidance) (available at: *https://www.fda.gov/media/82716/download*), implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in NDAs, ANDAs, certain BLAs, and certain INDs submitted to CBER or the Center for Drug Evaluation and Research by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify any new standards and version