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

updates to FDA-supported study data standards that will be added to the Catalog, when the support for such standards and version updates begins or ends, and when the requirement to use such standards and version updates in submissions begins or ends.

Support for CDISC SENDIG–AR v1.0 begins March 26, 2024. The requirement for electronic submissions to be submitted using CDISC SENDIG–AR v1.0 begins for studies that start after March 15, 2027, for NDAs, ANDAs, certain BLAs, and certain INDs.

Dated: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06294 Filed 3–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias (ADRD) on people with the disease and their caregivers. During the meeting on April 29 and April 30, 2024, the Advisory Council will hear updates from federal agencies on activities during the last quarter and from panels organized by the clinical care and long-term services and supports subcommittees. On the first day, presenters will discuss care and navigation across healthcare settings from post-diagnosis through advanced disease. The panels on the second day will focus on challenges with long-term services and supports for people with young-onset dementia and their care partners/families, as well as challenges with dementia among aging populations experiencing homelessness or incarceration.

DATES: The meeting will be April 29, 2024, from 9:00 a.m. to 4:30 p.m. EST and April 30, 2024, from 9:00 a.m. to 1:00 p.m. EST.

ADDRESSES: The meeting will be a hybrid of in-person and virtual. The meeting will be held in Room 800 of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. It will also stream live at *www.hhs.gov/live.*

Comments: Time is allocated on the agenda to hear public comments from 4:00 p.m. to 4:30 p.m. on Monday, April 29. The time for oral comments will be limited to two (2) minutes per individual. To provide a public comment, please register by emailing your name to *napa@hhs.gov* by Wednesday, April 24. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. *Note:* There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:45 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. Public commenters will not be admitted to the virtual meeting before 3:30 p.m. but are encouraged to watch the meeting at *www.hhs.gov/live.* Should you have questions during the session, please email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

To ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Wednesday, May 1, 2024. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Wednesday, May 1, 2024, to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov. Note:* The meeting will be available to the public live at *www.hhs.gov/live.*

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: Alzheimer's disease-related dementias, clinical care, long term care support services, young-onset dementia, homelessness, incarceration.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available after the meeting. This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. Participants joining in person should note that seating may be limited. Those wishing to attend the meeting in person must send an email to *napa@hhs.gov* and put ''April 29–30 Meeting Attendance'' in the subject line by Wednesday, April 24 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: March 14, 2024.

Miranda Lynch-Smith,

Deputy Assistant Secretary for Human Services Policy, Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2024–06405 Filed 3–25–24; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.