CFR part 601 regarding applicable manufacturing information for BLAs are approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27309 Filed 12–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5022]

Data Standards; Support and Requirement Begins for the Clinical Data Interchange Standards Consortium Version 2.0 of the Study Data Tabulation Model, Version 3.4 of the Study Data Tabulation Model Implementation Guide, and Version 1.0 of the Standard for Exchange of Nonclinical Data Implementation Guide—Genetox; Requirement Ends for the Clinical Data Interchange Standards Version 3.2 of the Study Data Tabulation Model Implementation Guide

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) and Center for Drug Evaluation and Research (CDER) are announcing that support begins for version 2.0 of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTMv2.0), version 3.4 of the CDISC Study Data Tabulation Model Implementation Guide (SDTMIGv3.4), and version 1.0 of the Standard for Exchange of Nonclinical Data Implementation Guide—Genetox (SENDIG-Genetoxv1.0) and announcing the date that these version updates are required in certain submissions. CBER and CDER are also announcing the date that requirement ends for version 3.2 of the CDISC SDTMIG (SDTMIGv3.2). The Agency will update the FDA Data Standards Catalog (Catalog) to reflect these changes. The Agency will publish in the technical specifications document entitled ''Study Data Technical Conformance Guide'' additional details on how to implement new variables.

DATES: Support for version CDISC SDTMv2.0, SDTMIGv3.4, and SENDIG-Genetoxv1.0 begins December 13, 2023.

The requirement for electronic submissions to be submitted using CDISC SDTMv2.0, SDTMIGv3.4, and SENDIG-Genetoxv1.0 begins March 15, 2025, for new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs). The requirement for electronic submissions to be submitted using version CDISC SDTMIGv3.2 ends December 13, 2023.

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–2023–N–5022 for ''Data Standards; Requirement Begins for the Clinical Data Interchange Standards Consortium Version 2.0 of the Study Data Tabulation Model and Version 3.4 of the Study Data Tabulation Model Implementation Guide; Requirement Ends for the Clinical Data Interchange Standards Version 3.2 of the Study Data Tabulation Model Implementation Guide.'' 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: *CDER:* Helena Sviglin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 240–402–6511, *cderdatastandards@fda.hhs.gov.*

CBER: Lisa Lin and Anne Taylor, 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, *CBER-eDATA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA's CBER and CDER are issuing this **Federal Register** notice to announce the date that support begins for CDISC SDTMv2.0, SDTMIGv3.4, and SENDIG-Genetoxv1.0 and requirement ends for version 3.2 of the CDISC SDTMIG. 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 CDER 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 SDTMv2.0, SDTMIGv3.4, and SENDIG-Genetoxv1.0 begins December 13, 2023. The transition date for these version updates is March 15, 2024. The requirement for electronic submissions to be submitted using CDISC SDTMv2.0, SDTMIGv3.4, and SENDIG-Genetoxv1.0 is March 15, 2025, for NDAs, ANDAs, certain BLAs, and certain INDs. The requirement for electronic submissions to be submitted using version 3.2 of the CDISC SDTMIG ends December 13, 2023.

Dated: December 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27310 Filed 12–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations for Voting Members for the Genetic Metabolic Diseases Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for voting members excluding consumer and industry representatives, to serve on the Genetic Metabolic Diseases Advisory Committee (the Committee) in the Center for Drug Evaluation and Research. Nominations will be accepted for current vacancies effective with this notice. FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before February 12, 2024 will be given first consideration for membership on the Committee. Nominations received after February 12, 2024 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* and selecting Academician/Practitioner from the dropdown menu (regardless of whether Academician/Practitioner accurately describes the nominee), or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Moon Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2894, email: *GEMDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members to fill current vacancies on the Genetic Metabolic Diseases Advisory Committee. This notice does not include consumer and industry representative nominations. The Agency will publish two separate notices announcing the vacancy of a representative of consumer interests and the vacancy of a representative of industry interests.

I. General Description of the Committee Duties

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug and biologic products for use in the treatment of genetic metabolic diseases and makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of medical genetics, manifestations of inborn errors of metabolism, small population trial design, translational science, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve either as Special Government Employees or non-voting representatives. Federal members will serve as Regular Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee with the exception of the following: individuals who are not U.S. citizens or nationals cannot be appointed as Advisory Committee Members (42 U.S.C. 217(a))