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**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](mailto: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](mailto: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](mailto: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))

in FDA. Self-nominations are also accepted. Nominations must include a cover letter; a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: December 7, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-27301 Filed 12-12-23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0008]

#### Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. FDA seeks to include the views of individuals on its advisory committee regardless of their gender identification, religious affiliation, racial and ethnic identification, or disability status and, therefore, encourages nominations of appropriately qualified candidates from all groups.

**DATES:** Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by January 29, 2024, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by January 29, 2024. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2023.

**ADDRESSES:** All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to [ACOMSSubmissions@fda.hhs.gov](mailto:ACOMSSubmissions@fda.hhs.gov) or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002. Additional information about becoming a member of 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:** For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002, 301-796-8220, [Kimberly.Hamilton@fda.hhs.gov](mailto:Kimberly.Hamilton@fda.hhs.gov).

For questions relating to specific advisory committees or panels, contact the appropriate contact person listed in table 1.

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Rakesh Raghuvanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993-0002, 301-796-4769, <a href="mailto:Rakesh.Raghuvanshi@fda.hhs.gov">Rakesh.Raghuvanshi@fda.hhs.gov</a> .	FDA Science Board Advisory Committee.
Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1226, Silver Spring, MD 20993-0002, 240-402-8006, <a href="mailto:Prabhakara.Atreya@fda.hhs.gov">Prabhakara.Atreya@fda.hhs.gov</a> .	Allergenic Products Advisory Committee.
Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993-0002, 301-796-2894, <a href="mailto:MoonHee.Choi@fda.hhs.gov">MoonHee.Choi@fda.hhs.gov</a> .	Anesthetic and Analgesic Drug Products Advisory Committee, Non-Prescription Drugs Advisory Committee.
She-Chia Jankowski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6178, Silver Spring, MD 20993-0002, 240-402-5343, <a href="mailto:She-Chia.Jankowski@fda.hhs.gov">She-Chia.Jankowski@fda.hhs.gov</a> .	Antimicrobial Drugs Advisory Committee.
Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2412, Silver Spring, MD 20993-0002, 301-796-7699, <a href="mailto:Jessica.Seo@fda.hhs.gov">Jessica.Seo@fda.hhs.gov</a> .	Peripheral and Central Nervous System Drugs Advisory Committee.
Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2510, Silver Spring, MD 20993-0002, 301-796-9034, <a href="mailto:Yvette.Waples@fda.hhs.gov">Yvette.Waples@fda.hhs.gov</a> .	Cardiovascular and Renal Drugs Advisory Committee, Medical Imaging Drugs Advisory Committee.