



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0008]

Request for Nominations of Individuals and Industry Organizations 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 that industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Genetic Metabolic Diseases Advisory Committee (the Committee) in the Center for Drug Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve on the Committee. Nominees recommended to serve as a nonvoting industry representative may either be self-nominated or nominated by an industry organization. Nominations will be accepted for the current vacancy effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest, must send a letter stating that interest to the FDA by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], (see sections I and II of this document for details). Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: All statements of interest from interested industry organizations interested in participating in the selection process of a nonvoting industry representative should be sent electronically to Nicholas Marsh (see **FOR FURTHER INFORMATION CONTACT**). All nominations for the nonvoting industry representative may be submitted electronically by accessing 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, 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: Nicolas Marsh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2418, Silver Spring, MD 20993-0002, 240-402-5357, email: nicholas.marsh@fda.hhs.gov.

For questions relating to the Genetic Metabolic Diseases Advisory Committee: 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 nominations for a nonvoting industry representative for the Genetic Metabolic Diseases Advisory Committee.

Elsewhere in this issue of the *Federal Register*, FDA is publishing separate documents regarding:

1. Genetic Metabolic Diseases Advisory Committee; Notice of Establishment
2. Request for Nominations for Voting Members for the Genetic Metabolic Diseases Advisory Committee
3. Request for Nominations of Individuals and Consumer Organizations for the Genetic Metabolic Diseases Advisory Committee

I. General Description of the Genetic Metabolic Diseases Advisory Committee's 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. Qualifications

Persons nominated for the Committee should be full-time employees of firms that develop human drug and biologic products, or consulting firms that represent human drug and biologic product developers or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest must send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 60 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current résumés or *curriculum vitae*. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, to represent industry interest for the committee, within 60 days after the receipt of the FDA letter. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select temporary nonvoting members to represent industry interests.

IV. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a temporary nonvoting industry representative. Nominations must include a cover letter and 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 Committee Membership Nomination Portal (see **ADDRESSES**). Nominations should specify the advisory committee for which the nominee is recommended within 60 days of publication of this document (see **DATES**). Nominations should also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Only interested

industry organizations participate in the selection process. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

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.

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.

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