



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-0008]

### Request for Nominations from Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Cellular, Tissue, and Gene Therapies Advisory Committee

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the CTGTAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent via

email to Cicely Reese or Marie DeGregorio (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives must be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. 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:** Cicely Reese or Marie DeGregorio, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1232, Silver Spring, MD 20993-0002, 240-620-9987, email: [CBERCTGTAC@fda.hhs.gov](mailto:CBERCTGTAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

#### I. Cellular, Tissue, and Gene Therapies Advisory Committee

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products, which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

#### II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter via email 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 30 days, FDA will

send a notification 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. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. 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 the nonvoting member to represent industry interests.

### III. Application Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee, including current business address and telephone number, 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**) within 30 days of publication of this document (see **DATES**). Nominations must also 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 forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of women and men, 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: January 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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