

in the body of your comments and you must identify the 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:** 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, [GEMDAC@fda.hhs.gov](mailto:GEMDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Genetic Metabolic Diseases Advisory Committee (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.

The Committee shall consist 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.

Elsewhere in this issue of the **Federal Register**, FDA is publishing separate documents regarding: (1) Genetic Metabolic Diseases Advisory Committee: Request for Nominations for Voting Members on a Public Advisory Committee; Genetic Metabolic Diseases Advisory Committee; (2) Request for Nomination of Individuals and Consumer Organizations for the Genetic Metabolic Diseases Advisory Committee; and (3) Request for Nomination of Individuals and Industry Organizations for the Genetic Metabolic Diseases Advisory Committee.

FDA intends to publish in the **Federal Register** a final rule adding the Genetic Metabolic Diseases Advisory Committee to 21 CFR 14.100.

Dated: December 7, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-27304 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 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 *February 12, 2024*, (see sections I and II of this document for details). Concurrently, nomination materials for prospective candidates should be sent to FDA by *February 12, 2024*.

**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:

Nicholas 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](mailto: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](mailto: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.*

[FR Doc. 2023-27303 Filed 12-12-23; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Applications for Deemed Public Health Service Employment With Liability Protections Under the Federal Tort Claims Act for Health Centers, Deemed Health Center Volunteers, and Free Clinic Sponsored Individuals, OMB No. 0906-XXXX-New**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than February 12, 2024.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Applications for Deemed Public Health Service (PHS) Employment with Liability Protections Under the Federal Tort Claims Act (FTCA) for Health Centers, Deemed Health Center Volunteers, and Free Clinic Sponsored Individuals, OMB No. 0906-XXXX-New.

*Abstract:* Section 224(g)-(n) of the PHS Act (42 U.S.C. 233(g)-(n)) states that entities receiving funds under section 330 of the PHS Act and specified individuals of that entity may be deemed to be PHS employees for the purpose of eligibility for liability protections, including FTCA coverage, for the performance of medical, surgical, dental, and related functions within the scope of deemed employment upon approval of an application for deemed employment. The Health Center Program and Health Center FTCA Program are administered by HRSA. Health centers submit deeming applications annually to HRSA in the prescribed form and manner in order to obtain deemed PHS employee status, with the associated eligibility for FTCA coverage. Such applications must be approved by HRSA in a Notice of Deeming Action. Deemed health centers must resubmit applications annually meeting all deeming requirements in order to maintain deemed status.

### Volunteer Health Professionals (VHPs)

Section 224(q) of the PHS Act (42 U.S.C. 233(q)) extends eligibility for deemed PHS employee status to VHPs sponsored by deemed health centers upon approval of an individual sponsorship application for deemed PHS employment. The Health Center VHP FTCA Program is administered by HRSA. In order to maintain deemed status for VHPs, deemed health centers must submit to HRSA an annual deeming sponsorship application on behalf of individually named VHPs. For liability protections to apply, such