Patient Experience Data; Request for Information and Comments'' notice published on May 2, 2023. The input received in response to the Request for Information will help FDA plan two public workshops focused on methodological challenges and will help FDA identify priorities for future work.

FOR FURTHER INFORMATION CONTACT: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the seventh iteration of the Prescription Drug User Fee Act, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development and, as appropriate, regulatory decision making. This included issuing a Request for Information (RFI) available at *https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments* to elicit public input on methodologic challenges related to patient experience data encountered by stakeholders, and other areas of greatest interest or concern to public stakeholders.[1] The RFI was published on May 2, 2023, and the public comment period was open until July 3, 2023. A summary of the comments received can be found in the in the public docket or by going to *https://www.regulations.gov* and entering the following docket number: FDA–2023–N–1506.

II. Electronic Access

Persons with access to internet may obtain the summary within the public docket at *https://www.regulations.gov/docket/FDA-2023-N-1506.*

[1] The Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act (Pub. L. 114–255) and the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52), defines patient experience data as data that are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers) and are intended to provide information about patients' experiences with a disease or condition, including the impact (including physical and psychosocial impacts) of such disease or condition or a related therapy or clinical investigation and patient preferences with respect to treatment of the disease or condition.

Dated: December 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27312 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–4917]

Advisory Committee; Genetic Metabolic Diseases Advisory Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of establishment.

SUMMARY: Under the Federal Advisory Committee Act, the Food and Drug Administration (FDA) is announcing the establishment of the Genetic Metabolic Diseases Advisory Committee. The Commissioner of Food and Drugs (Commissioner) has determined that it is in the public interest to establish such a committee. Duration of this committee is 2 years from the date the Charter is filed, unless the Commissioner formally determines that renewal is in the public interest.

DATES: Either electronic or written comments on the notice must be submitted by February 12, 2024. FDA is establishing a docket for public comment on this document. The docket number is FDA–2023–N–4917. The docket will close on February 12, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 12, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–4917 for ''Advisory Committee; Genetic Metabolic Diseases Advisory Committee; Establishment.'' Received comments, those filed in a timely manner, 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.'' FDA 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 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 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*.

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: 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