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 to 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 this 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: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993, 301–796–9208, *Ethan.Gabbour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the seventh iteration of the Prescription Drug User Fee Act (PDUFA VII), incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to continue to strengthen capacity to facilitate development and use of patient-focused methods to inform drug development and regulatory decisions, including issuing this Request for Information (RFI) to elicit public input on methodologic challenges encountered by stakeholders, and other areas of greatest interest or concern to public stakeholders. These methodologic challenges may be related to the collection and analysis of patient experience data, generally, or they may be related more specifically to the submission and evaluation of patient experience data in the context of FDA's benefit-risk assessment or product labeling.

The feedback received as part of this RFI will be summarized in a subsequent **Federal Register** document and will help to inform future public workshops focused on methodologic challenges related to patient-focused drug development. 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 (1) are collected by any persons (including patients, family members, and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and (2) are intended to provide information about patients' experiences with a disease or condition, including (A) the impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy or clinical investigation, on patients' lives; and (B) patient preferences with respect to treatment of such disease or condition.'' [1]

II. Request for Information and Comments

Interested persons are invited to provide detailed information and comments on methodological challenges relating to patient experience data, including the submission and evaluation of patient experience data in the context of the benefit-risk assessment and product labeling. Please provide the rationale for any suggestions and include supporting data if available. FDA is particularly interested in information related to the following:

(1) Describe any perceived barriers to the use of patient experience data for regulatory decision making (*e.g.,* benefit-risk assessment, product labeling).

(2) Describe any challenges and limitations experienced when selecting, modifying, or developing fit-for-purpose Clinical Outcome Assessment measures.

(3) Describe any challenges and statistical analysis considerations when constructing and selecting endpoints of interest and in understanding whether an estimated treatment effect corresponds to a real difference in patients' lives.

(4) Describe any challenges and limitations experienced when developing and conducting patient preference studies to support regulatory submissions.

(5) Describe any challenges and limitations when submitting patient experience data to FDA.

[1] Patient experience data is defined for purposes of this guidance in Title III, section 3001 of the 21st Century Cures Act, as amended by section 605 of FDARA, *https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf.*

The public comments collected will help FDA plan two workshops focused on methodological challenges with patient experience data and will identify opportunities for future work.

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09265 Filed 5–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1259]

Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches; Public Workshop; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches'' that appeared in the **Federal Register** of April 24, 2023. The document announced a public workshop. The document was published with an incorrect topic for discussion. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Legislation, and International Affairs, Food and Drug Administration, 301–796–9115, *Lisa.Granger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of April 24, 2023, in FR Doc. 2023–08545 (88 FR 24807), on page 24808, the following correction is made:

- On page 24808, in the second column, in Section II, ''Topics for Discussion at the Public Workshop,'' the fifth topic, ''Science- and risk-based approaches for developing and accessing innovative technologies across platform products and sites to streamline adoption.'' is corrected to read ''Science- and risk-based approaches for developing and assessing innovative technologies across platform products and sites to streamline adoption.''

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09206 Filed 5–1–23; 8:45 am]

BILLING CODE 4164–01–P