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* 14. Yang, M., ''A Psychiatrist's Perspective on the Digital Pill,'' *KevinMD.com,* December 2, 2017, available at *https://www.kevinmd.com/blog/2017/12/psychiatrists-perspective-digital-pill.html,* accessed May 16, 2022.

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09268 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–2019–D–0362]

A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers; Guidance for Industry; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 12, 2023. The document announced the availability of a final guidance entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers; Guidance for Industry.'' The notice of availability for this final guidance was published with an incorrect OMB control number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Mona Shing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3355, Silver Spring, MD 20993–0002, 301–796–0910.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 12, 2023 (88 FR 22038), in FR Doc. 2023–07687, the following correction is made:

1. On page 22040, in the first column, in the last sentence of ''II. Paperwork Reduction Act of 1995,'' the OMB control number 0910–0733 is corrected to read: ''. . .and the collections of information in FDA's guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0014.'' The correction changes the OMB control number from a number that was discontinued to an active one.

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09264 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–1506]

Methodological Challenges Related to Patient Experience Data; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on methodological challenges related to patient experience data in the context of the benefit-risk assessment and product labeling, and other areas of greatest interest or concern to public stakeholders. Public comments will help FDA plan two public workshops focused on methodological challenges and identify priorities for future work.

DATES: Although you can comment at any time, to ensure the Agency considers your comment in our development of the workshops, submit either electronic or written information and comments by July 3, 2023.

ADDRESSES: You may submit comments and information at any time as follows:

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–1506 for ''Methodological Challenges Related to Patient Experience Data.'' Received comments 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.'' The Agency 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 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