

• **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: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993-0002, 240-402-8926 or 301-796-2500, dat.doan@fda.hhs.gov; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301-796-9567, Paul.Kluetz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 6, 2024, FDA published a notice of availability with a 60-day comment period to

request comments on the draft guidance for industry entitled “Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.” The Agency has received requests for a 30-day extension of the comment period. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance.

FDA has considered the requests and is extending the comment period for 30 days, until March 6, 2025. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments on this draft guidance.

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3595]

Agency Information Collection Activities; Proposed Collection; Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification; Withdrawal of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a notice that was published in the **Federal Register** of October 18, 2023.

DATES: The notice is withdrawn on January 17, 2025.

FOR FURTHER INFORMATION CONTACT:

Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6206, Silver Spring, MD 20993-0002, 240-402-0978.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 18, 2023 (88 FR 71875), “Agency Information Collection Activities; Proposed Collection; Comment Request: Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey

Instrument Format to Minimize Misclassification.” FDA requested comment on the information collection associated with the proposed study entitled “Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.”

Under the Paperwork Reduction Act of 1995, Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

In the October 18, 2023, **Federal Register** notice, FDA proposed a new collection of information. However, FDA no longer intends to proceed with the proposed study due to circumstances and timing surrounding the execution of the study. Therefore, we are withdrawing the October 18, 2023 notice.

Dated: January 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5468]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration’s Adverse Event and Product Experience Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA’s