Labeling/RulesRegulationsGuidance/default.htm, or *https://www.regulations.gov.*

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22976 Filed 10–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3595]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed information collection entitled ''Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.''

DATES: Either electronic or written comments on the collection of information must be submitted by December 18, 2023.

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 December 18, 2023. 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–3595 for ''Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this

requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format To Minimize Misclassification

OMB Control Number 0910–NEW

FDA has a need for valid, high-quality surveillance data on misuse of pharmaceutical products and use of other substances in the United States. FDA is funding the evaluation and improvement of the data validity and reliability of the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) Substance Abuse Treatment Center Programs Combined (TCPC) survey. The RADARS TCPC is comprised of two unique programs, the Opioid Treatment Program and the Survey of Key Informants' Patients Program. These two programs use the same core paper data collection form and complement each other by providing information from patients entering both private and public opioid addiction treatment programs. Patients enrolling in the study complete a self-administered anonymous questionnaire, within the first week of admission. The objective of these programs is to provide timely prevalence estimates of abuse of legal and illegal opioids and other substances, within the past month, among patients enrolling in treatment primarily for opioid use disorders. Surveillance data collected by these programs are used by FDA as well as researchers, industry, and other public health stakeholders to inform policy and regulatory decisions. FDA will be providing public health expertise on the survey validity and reliability questions before implementation to ensure that they generate quality data. FDA will also be providing its expert input on the results, analysis, and interpretation, as well as how the survey may be improved in light of the results.

This FDA-funded information collection will include three survey arms, two arms focused on survey validity (is the survey measuring what it is intended to measure) and the third arm focused on survey reliability (do the questions consistently produce the same results when asked at different time points and in a different format). For both survey validity arms—a digital survey only and digital survey plus interview arm—volunteer participants will be asked to pause after answering each survey question to answer a series of content validation questions concerning comprehension and quality of survey items. Items assessed will include survey instructions, active pharmaceutical ingredient and product content, reason for use, and route of administration. For the survey reliability arm, TCPC paper survey participants at selected sites will be invited to voluntarily participate in a second, digital survey, and the results of the two survey formats will be compared. The data collected through the three arms of this information collection will be analyzed to validate the content of a modified TCPC survey and to then determine the reliability among a proxy population for the target population. Results from the three arms will inform the format, structure, and wording of the modified digital TCPC survey, prior to its launch.

The annual participant burden hours requested are based on the number of collections FDA expects the contractor to conduct over the requested time frame for this clearance. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent/interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content Validity—Digital Survey Arm	175	1	175	0.25 (15 minutes)	44
Content Validity—Digital Survey and Cognitive Interview Arm.	25	1	25	1.5 (90 minutes)	38
Reliability Survey Arm—Digital Survey	250	1	250	0.33 (20 minutes)	83
Total	450		450		165

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22966 Filed 10–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0465; FDA–2023–N–1529; FDA–2010–N–0583; FDA–2020–N–0145; FDA–2023–N–0918; FDA–2014–N–1721]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD