collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information for the De Novo Classification Process (Evaluation of Automatic Class III Designation) have been approved under OMB control number 0910–0844; and the collections of information in the guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756. The collections of information in 21 CFR part 314 (Applications for FDA Approval to Market a New Drug) and 21 CFR part 601 (General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension) have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28262 Filed 12–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1146]

Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.'' This guidance provides considerations for sponsors proposing to design a registry or to use an existing registry to support regulatory decision-making about a drug's effectiveness or safety. FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance on the use of RWE in regulatory decision-making. This guidance finalizes the draft guidance of the same title issued on November 30, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on December 22, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2021–D–1146 for ''Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3226, Silver Spring, MD 20993–0002, 301–796–3161, or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.'' FDA is issuing this guidance as part of its RWE Program and to satisfy, in part, the mandate under section 505F of the FD&C Act (21 U.S.C. 355g) to issue final guidance about the use of RWE in regulatory decision-making. Topics covered in this guidance include:

- Considerations regarding a registry's fitness-for-use in regulatory decision-making, focusing on attributes of a registry that support the collection of relevant and reliable data;
- Considerations when linking a registry to another data source for supplemental information, such as data from medical claims, electronic health records, digital health technologies, or other registries; and
- Considerations for supporting FDA review of submissions that include registry data.

Section 3022 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) amended the FD&C Act to add section 505F, Utilizing Real World Evidence. In addition, the Prescription Drug User Fee Amendments of 2017 (PDUFA VI) committed FDA to publish draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions. In 2018, FDA created an RWE Framework and Program to evaluate the potential use of RWE to help support the approval of a new indication for a drug already approved under the FD&C Act or to help support or satisfy postapproval study requirements. In late 2021, FDA utilized the RWE Program to issue draft guidances outlining considerations for the use of real-world data and RWE in regulatory decision-making to satisfy the Cures Act mandate and the PDUFA VI commitment.

This guidance finalizes the draft guidance of the same title issued on November 30, 2021 (86 FR 67956). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include noting that sponsors proposing to use registry data to support regulatory decision-making by FDA are responsible for ensuring that attributes of the registry support the collection of relevant and reliable data, including in situations where the data are from a registry not managed or designed by the sponsor, and sponsors should have access to the metadata associated with the registry data. In addition, statements were added to note that registry data are sometimes used to evaluate a drug received during routine medical practice, such as to evaluate clinical outcomes in populations underrepresented in clinical trials, to note that registries should have a plan to reduce missing assessments and minimize loss to followup of participants, and to provide additional considerations related to linkage to other data sources. Examples of pregnancy-related information that may be collected by a registry were removed because this information is addressed in a separate guidance. Terms that may be defined differently by different stakeholders were removed from the guidance if they were not necessary to understand the content of the guidance. Other relevant definitions were transferred from the glossary to the text. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 310 and 314 have been approved under OMB control number 0910–0230. The collections of information in 21 CFR parts 310, 314, and 600 have been approved under OMB control number 0910–0291. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 600 have been approved under OMB control number 0910–0308. The collections of information resulting from formal meetings between sponsors or applicants and FDA have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/*

search-fda-guidance-documents, or *https://www.regulations.gov.*

Dated: December 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28289 Filed 12–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0548]

Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data.'' This guidance provides recommendations to sponsors to help support compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) when submitting study data derived from real-world data (RWD) sources in applicable regulatory submissions using standards specified in the Data Standards Catalog. FDA is publishing this guidance as part of a series of guidance documents under its program to evaluate the use of real-world evidence (RWE) in regulatory decision making. This guidance finalizes the draft guidance of the same title issued on October 22, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on December 22, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2021–D–0548 for ''Data Standards for Drug and Biological Product Submissions Containing Real-World 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–3161; or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data.'' Section 3022 of the 21st Century Cures Act (Cures Act) amended the FD&C Act to add section 505F, Utilizing Real World Evidence (21 U.S.C. 355g). In addition, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA committed to publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in