To effectively monitor the program, Part D plans will be required to report data elements related to the program at the beneficiary, contract, and Plan Benefit Package (PBP)1 levels beginning in Contract Year (CY) 2025. In this information collection package, CMS addresses the proposal to require Part D plans to submit beneficiary-level data elements into the MARx system via a program-specific transaction (separate from the enrollment file). In accordance with the Plan Communication User Guide (PCUG), plans may submit multiple transaction files during any CMS business day, Monday through Friday. Plan transactions are processed as received; there is no minimum or maximum limit to the number of files that Plans may submit in a day. In general, transaction and processing occur throughout the Current Calendar Month (CCM). For CY 2025, CMS will not require independent data validation for this new MARx reporting requirement. *Form Number:* CMS–10887 (OMB control number: 0938-New); *Frequency:* Monthly; *Affected Public:* Private, Federal Government, Business or other for profits, Not-for-profits institutions; *Number of Respondents:* 856; *Total Annual Responses:* 3,200,856; *Total Annual Hours:* 59,958. (For policy questions regarding this collection contact Michael Brown at (872) 287–1370 or *michael.brown3@cms.hhs.gov.*)

Dated: January 23, 2024.

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–01582 Filed 1–25–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3768]

Best Practices for Food and Drug Administration Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products; Final Document; 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 document entitled ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products.'' The 21st Century Cures Act (Cures Act), enacted on December 13, 2016, requires that FDA make publicly available on its internet website best practices for certain postmarketing drug safety surveillance activities. This final document sets forth risk-based principles for FDA's conduct of ongoing postmarketing safety surveillance for human drug products and human biological products, in part, to address the Cures Act requirements. This document finalizes the draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff'' that was issued on November 7, 2019.

DATES: The announcement of the final document is published in the **Federal Register** on January 26, 2024.

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–2019–N–3768 for ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human 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 document 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, 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 document.

FOR FURTHER INFORMATION CONTACT: Sara Camilli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3486, Silver Spring, MD 20993–0002, 301–796–4203, *Sara.Camilli@fda.hhs.gov;* 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 final document entitled ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products.''

Title IX, section 915 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) added section 505(r) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(r)), requiring FDA to prepare a summary analysis of the adverse drug reaction reports received for a drug by 18 months after approval or after use of the drug by 10,000 individuals, whichever is later. The analysis includes identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number.

Section 3075 of the Cures Act (Pub. L. 114–255) amended section 505(r)(2)(D) of the FD&C Act to eliminate the requirement for summary analyses for drugs as required by FDAAA. In place of the summary analyses, section 3075 amended section 505(r)(2)(D) of the FD&C Act to include the requirement that FDA make publicly available on its internet website best practices for drug safety surveillance activities for drugs approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act).

Section 3075 of the Cures Act also amended section 505(k)(5) of the FD&C Act to strike ''bi-weekly screening,'' in subparagraph (A), and insert ''screenings''; it also added the requirement that FDA make publicly available on its internet website guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System.

The final document entitled ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drugs and Biological Products'' sets forth risk-based principles for FDA's conduct of ongoing postmarketing safety surveillance for human drug products and human biological products to address the Cures Act requirements. Although section 3075 of the Cures Act only references drugs approved under section 505 of the FD&C Act or section 351 of the PHS Act, the document additionally discusses other products, including nonprescription drug products, compounded drug products, and homeopathic products. The document also includes a high-level overview of other drug safety surveillance data sources, tools, methods, and activities that extend beyond use of FDA's adverse event reporting systems, as well as regulatory and other actions that can be taken in response to identified safety signals. These additional topics are included to provide context and a general overview of FDA's safety surveillance process.

This document finalizes the draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff,'' issued on November 7, 2019 (84 FR 60094). FDA considered comments received on the draft document as the document was finalized. Changes from the draft to the final document include: (1) document title revised to emphasize this document's focus on postmarketing safety surveillance and to clarify that this document only refers to human drug and biological products that are regulated by FDA, as this document does not refer to animal drugs regulated by FDA; (2) additional content to distinguish between the use of the terms *adverse event* and *adverse reaction;* (3) clarification of products that generally are subject to more extensive monitoring and types of safety information for focus; (4) addition of a description of the FDA Adverse Event Reporting System Public Dashboard; (5) revisions to the content on medication errors, for clarity; (6) revisions to the section on the pregnant population to align with the most recently issued documents pertaining to clinical trials and postapproval pregnancy safety studies; (7) inclusion of citations referencing the Sentinel System; (8) revisions to the description of the process for signal evaluation and documentation, including addition of a reference to the Center for Drug Evaluation and Research's ''Manual of Policies and Procedures for Collaborative Identification, Evaluation, and Resolution of a Newly Identified Safety Signal''; (9) inclusion of an expanded discussion of product labeling changes; and (10) additional content regarding Drug Safety Communications. Editorial changes were made to improve clarity.

II. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and-epidemiology* or *https://www.regulations.gov.*

Dated: January 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01584 Filed 1–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2853]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 26, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information