collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information related to the protection of human subjects under 21 CFR part 50 have been approved under OMB control number 0910–0130. 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.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01197 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3112]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Adverse Experience Reporting

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 18, 2025.

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 collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0230. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Adverse Experience Reporting

OMB Control Number 0910–0230—Revision

This information collection helps support provisions found in sections 201, 502, 505, 701, and 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 352, 355, 371, and 379aa) governing adverse experience reporting (AER) and associated recordkeeping for FDA-regulated drug products. FDA has issued applicable regulations in part 4 and §§ 310.305, 314.80, 314.81, 314.98, and 329.100 (21 CFR part 4 and 21 CFR 310.305, 314.80, 314.81, 314.98, and 329.100) that implement the statutory requirements, identify specific content and format elements, and establish reporting and retention schedules for the required information. Postmarketing safety data collection and adverse event reporting are critical elements of FDA's monitoring of drugs. For more information, please visit *https://www.fda.gov/drugs/surveillance/postmarketing-adverse-event-reporting-compliance-program.*

Respondents to the information collection are manufacturers, packers, distributors, and applicants of FDA-regulated drug and biologic products marketed with or without an FDA-approved application, including over-the-counter (OTC) drug products marketed without an approved application; OTC drug products marketed under the OTC Drug Monograph Review process (whether subject to a final monograph or not); and drug products marketed outside the monograph system. All reports and followup reports must be submitted to FDA in electronic format, although waivers of the electronic requirements are available for good cause.

Adverse experience reporting for products associated with drug marketing applications are governed by regulations in §§ 314.80, 314.81, and 314.98. The regulations identify required reporting content and format elements, as well as establish followup reporting requirements and mandatory reporting schedules. The regulations also establish associated recordkeeping and require that written procedures be developed for the surveillance, receipt, evaluation, and reporting of postmarketing adverse experiences to FDA. The regulations require reporting in an electronic format that FDA can process, although temporary waivers may be granted on a limited basis for good cause. A final guidance for industry entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports'' (April 2022) is available for general information pertaining to electronic submission of postmarketing safety reports for certain human drugs, biological products, and combination products. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports.*

We have established and maintain the FDA Adverse Event Reporting System (FAERS) at *https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions.* Information may be submitted via FDA's Electronic Submissions Gateway or utilizing the ''Safety Reporting Portal,'' developed by FDA and the National Institutes of Health to streamline reporting and review of adverse events.

The primary purpose of FDA's adverse drug experience reporting system is to enable identification of signals for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed product provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, clinical investigators, and literature. Information derived from the adverse drug experience reporting system contributes directly to increased public

health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning), to make decisions about risk evaluation and mitigation strategies; the need for postmarketing studies or clinical trials; and, when necessary, to initiate removal of a product from the market.

In the **Federal Register** of September 23, 2024 (89 FR 77515), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2] [3]

21 CFR section or guidance; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5); AERs for prescription products not the subject of a marketing application	36	88.8	3,197	1	3,197
314.80(c)(1); 15-day alerts for approved products	682	1,832.84	1,250,000	1	1,250,000
314.80(c)(2); periodic reports for approved products	682	1,228.73	838,000	60	50,280,000
329.100; AERs for non-prescription drug products	312	62.522	19,507	6	117,042
ICH E2C(R2) Guidance; Periodic safety updates; Applicants w/waiver for an approved application (section III.A.)	471	8.885	4,185	1	4,185
ICH E2C(R2) Guidance; Periodic safety updates; Applicants w/no waiver for an approved application (section III.B.)	1,115	16.254	18,123	2	36,246
AER During Pandemic Guidance; notifying FDA when normal reporting is not feasible (section III.C.)	1	1	1	8	8
4.103, 4.104, 4.105, 310.305, 314.80, 314.98, 329.100(c); Waiver requests from electronic reporting requirements	1	1	1	24	24
Total	[4] 2,618		2,133,014		51,690,702

[1] There are no capital costs associated with this collection. The operating and maintenance costs associated with this collection of information are approximately $25,000 annually.

[2] The reporting burdens for § 310.305(c)(1), (2), and (3), and voluntary reports by healthcare providers received under § 314.80(c)(1)(i) and (ii) are covered under OMB control number 0910–0291.

[3] Totals may not sum due to rounding.

[4] Total of unique respondents.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section or guidance section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305; AER records—prescription product not the subject of a marketing application	36	88.8	3,197	16	51,152
314.80(j); AER records—product associated w/marketing application	841	1,814.0606	1,525,625	16	24,410,000
Postmarket AER for Nonprescription Drug Products Guidance; (§ 329.100)	312	62.5224	19,507	8	156,056
AERs During Pandemic Guidance; Continuity of operations planning (section III.B.)	100	1	100	50	5,000
AERs During Pandemic Guidance; documenting conditions and resultant high absenteeism (section III.C.2)	350	1	350	8	2,800
AERs During Pandemic Guidance; documenting AER process (section III.C.1.)	350	1	350	8	2,800
4.105; Postmarketing safety recordkeeping for combination products and constituent parts	11	18	198	0.1 (6 minutes)	19.8
Total			1,549,327		24,627,827.8

[1] There are no capital costs associated with this collection of information. There are operating and maintenance costs associated with this collection of information of approximately $22,000 annually.

[2] Totals may not sum due to rounding.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.103; Postmarketing Safety reporting for combination products—Sharing information with other constituent part applicants	11	18	198	0.35 (21 minutes)	69.3

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

All applicants who have received marketing approval for drug products (including combination products that are administered as drug products) are required to report serious, unexpected adverse drug experiences (15-day ''Alert reports'') (§ 314.80(c)(1)(i)), as well as followup reports (§ 314.80(c)(1)(ii)) to FDA. These include all foreign or domestic AERs as well as AERs based on information from applicable scientific literature and certain reports from post marketing studies. Section 314.80(c)(1)(iii) pertains to AERs submitted by nonapplicants.

For operational efficiency, we have adjusted this information collection and burden table to include all 15-day alert reports submitted by applicants, manufacturers, packers, and distributors. Voluntary reports from healthcare providers are included under OMB control number 0910–0291.

Under § 314.80(c)(2), applicants (including combination products that are administered as drug products) must also provide periodic reports of adverse drug experiences. For the reporting interval, a periodic report includes reports of serious, expected adverse drug experiences, all nonserious adverse drug experiences, and an index of these reports; a narrative summary and analysis of adverse drug experiences; an analysis of the 15-day Alert reports submitted during the reporting interval; and a history of actions taken because of adverse drug experiences. Under § 314.80(j), applicants must keep records of all adverse drug experience reports known to the applicant for 10 years.

For marketed prescription drug products without approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs), manufacturers, packers, and distributors of these products are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded to the manufacturers, packers, and distributors by FDA. Under § 310.305(g), each manufacturer, packer, and distributor shall maintain records of all adverse drug experiences required to be reported for 10 years. All 15-day Alert reports and followup reports must be submitted to FDA in electronic format.

Section 760 of the FD&C Act also provides for mandatory safety reporting for over-the-counter human drug products not subject to applications approved under section 505 of the FD&C Act (NDAs or ANDAs). These requirements apply to all OTC drug products marketed without an approved application, including those marketed under the OTC Drug Monograph Review process (whether or not subject to a final monograph), those marketed outside the monograph system, and including those that have been discontinued from marketing but for which a report of an adverse event was received. Under § 329.100, respondents must submit reports according to section 760 of the FD&C Act in an electronic format.

To assist respondents with implementation of section 760 of the FD&C Act, FDA developed the guidance for industry entitled ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application'' (July, 2009), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-nonprescription-human-drug-products-marketed-without-approved*. The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the FD&C Act, including how to submit these reports and followup reports under section 760(c)(2) of the FD&C Act. Section 760(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription drug adverse event reports, whether the event is serious or not, for a period of 6 years. FDA's guidance recommends that respondents maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports.

In addition, this information collection includes an *International Council for Harmonisation* of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance for industry entitled ''Providing Postmarketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report), (November 2016)'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-postmarket-periodic-safety-reports-ich-e2cr2-format-periodic-benefit-risk-evaluation*. The ICH E2C(R2) guidance describes the conditions under which applicants may use the ICH E2C(R2) Periodic Benefit-Risk Evaluation Report format for certain types of adverse event reporting.

FDA regulations in §§ 314.80(c)(2) and 600.80(c)(2) require applicants to submit postmarketing periodic safety reports for each approved application. The reports must be submitted quarterly for the first 3 years following the U.S. approval date and annually thereafter and must contain the information described in §§ 314.80(c)(2)(ii) and 600.80(c)(2)(ii) (the information collection associated with 21 CFR part 600—Biological Products, is approved under OMB control number 0910–0308). The Agency guidance assists respondents with satisfying the regulatory requirements in an alternative format, noting that the process differs depending on whether an applicable periodic safety update report waiver is in place.

Similarly, this information collection accounts for burden that may be applicable to the guidance document, ''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (May 2020),'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic*. In response to the Coronavirus Disease

2019 public health emergency, we revised the Agency guidance document to provide recommendations for recordkeeping applicable to any pandemic, not just influenza, including recommendations for planning, notification, and documentation for continuity of operations for firms that report postmarketing adverse events during any pandemic.

For operational efficiency, on March 20, 2023, OMB approved the addition of burden attributable to provisions related to postmarketing safety reporting for combination products as outlined in part 4, subpart B, and previously included in OMB control number 0910–0834. When information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of a combination product that includes a drug product, is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt under § 4.103 (21 CFR 4.103). Relatedly, 21 CFR 4.104 explains how and where to submit reports for combination products, and 21 CFR 4.105 provides for associated recordkeeping. For combination products that are administered as drug products with a constituent part, adverse event reports are submitted to the drug application under 21 CFR part 314, and constituent applicants are notified of the AER under § 4.103. These provisions are also described in the guidance document ''Postmarketing Safety Reporting for Combination Products'' (July 2019), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-safety-reporting-combination-products.*

Our estimates of the number of respondents and the total annual responses are based on reports submitted to the Agency. This information collection incorporates revisions to include the two guidances for industry regarding submission of adverse event reports (''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic'' and ''Providing Submissions in Electronic Format—Postmarketing Safety Reports'') and adjustments to include 15-day alert reports from applicants, manufacturers, distributors, and packers that were not recorded previously in this information collection. We also believe adjustments in the information collection reflect anticipated fluctuations in burden after pandemic conditions, adjustments by reporters' and changes in electronic reporting methodologies use of updated technology including updates and redefinitions of reporting software, and changes of company business practices over time. All reports and followup reports must be submitted to FDA in electronic format. Waivers of the electronic requirements are available. As a result of these revisions and adjustments, including the additional reports, the inclusion of guidance document recommendations and the consolidation of the burden from OMB control number 0910–0834 (previously added to this information collection March 2023), the total burden hours of the information collection have increased by 61,614,921 hours and 2,546,112 responses as compared to the previous renewal. While no changes have been made to the estimates in the 60-day notice, due to a clerical error, we are clarifying in this notice that the total burden hour increase is slightly lower (a difference of 198 burden hours and 89 responses).

Dated: January 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01151 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0001]

Optimizing Pregnancy Registries; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Optimizing Pregnancy Registries.'' The purpose of the public workshop is to discuss challenges in designing and implementing pregnancy registries and to consider innovative approaches to improve the design and conduct of pregnancy registries to inform the safety of drug and biological products during pregnancy. This public workshop is being held in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation program.

DATES: The public workshop will be held on March 27, 2025, from 9 a.m. to 4 p.m. eastern time and on March 28, 2025, from 9 a.m. to 12 p.m. eastern time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Room 1503), Silver Spring, MD 20993 and online. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, 301–796–6169, *OPRWorkshop@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Historically, pregnant individuals have been excluded from drug and biological product development. At the time of initial approval of a drug or biological product, there are generally limited data on the safety of the product when used during pregnancy. Therefore, postapproval pregnancy safety studies are needed to evaluate the safety of a product in the postapproval setting and to inform safety-related product labeling and clinical care.

Under the latest reauthorization of the Prescription Drug User Fee Act, FDA made a commitment to develop a framework describing how to optimally use data from different types of postapproval pregnancy safety studies. On September 18–19, 2023, FDA and the Duke-Margolis Institute for Health Policy convened a public workshop to discuss the design of postapproval pregnancy safety studies for drug and biological products.[1] Participants and interested parties discussed ways these studies can be optimized and different approaches that can be taken to bridge knowledge gaps in developing the framework. Although data were presented that suggest that pregnancy registry studies are an important source of pregnancy safety information, interested parties noted challenges with conducting single-drug, single-sponsor pregnancy registries, including low enrollment and long lag time to study completion. Similar to the Pregnant Women and Lactating Women recommendations,[2] interested parties identified the need to optimize disease-

[1] *https://healthpolicy.duke.edu/events/optimizing-use-postapproval-pregnancy-safety-studies.*

[2] *https://www.nichd.nih.gov/about/advisory/PRGLAC.*