

up wave. We will send invitations and study materials to sample respondents for up to eight follow-up waves (10 minutes per respondent). Including youth recruited in the replenishment, this will be up to 14,053 youth at each wave. At each of the eight follow-up waves, respondents are estimated to provide assent (5 minutes per respondent) and complete the survey (30 minutes per respondent). Where required, we will ask the parent/guardian to provide permission (5 minutes per respondent) for the youth to participate in the study. For youth who complete the survey, we will also mail an incentive letter (1 minute per respondent).

To align with Executive Order 14168, Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, we are revising this information collection to remove questions relating to gender. Since publication of the 60-day notice, the burden estimates have been updated. Overall, the estimated burden reflects a decrease of 455 burden hours and an increase of 507,886 responses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-09448 Filed 5-12-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-3098]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Experience Reporting

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, 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 postmarketing reporting and recordkeeping of adverse

experiences for drug and biological products.

DATES: Either electronic or written comments on the collection of information must be submitted by July 13, 2026.

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 July 13, 2026. 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-

2026-N-3098 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Experience Reporting." 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: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5683, PRASStaff@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, including each proposed extension of an existing 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.

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, review, and archive, 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 Monitoring System (AEMS), formerly the FDA Adverse Event Reporting System (FAERS). The FDA AEMS Electronic Submissions web page is available at <https://www.fda.gov/drugs/fda-adverse-event-monitoring-system-aems/fda-adverse-event-monitoring-system-aems-electronic-submissions>. Information may be submitted via FDA’s Electronic Submissions Gateway Next Generation or utilizing the FDA 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 heterogenous patient populations exposed to the marketed product provide the opportunity to collect information on rare, latent, and long-term effects. Data that contribute to 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; to determine the need for postmarketing studies or clinical trials; and, when necessary, to initiate removal of a product from the market.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN^{1 2 3}—Continued

21 CFR section or guidance; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
314.80(c)(2); ICSRs for serious, expected, and nonserious adverse drug experiences	682	1,228.73	838,000	1	838,000
314.80(c)(2); periodic reports for approved products	682	33.72	23,000	60	1,380,000
329.100; AERs for non-prescription drug products	312	62.522	19,507	6	117,042
<i>ICH E2C(R2) Guidance</i> ; Periodic safety updates; Applicants with waiver for an approved application (section III.A.)	471	8.885	4,185	1	4,185
<i>ICH E2C(R2) Guidance</i> ; Periodic safety updates; Applicants with no waiver for an approved application (section III.B.)	1,115	16.254	18,123	2	36,246
<i>AER During Pandemic Guidance</i> ; notifying FDA when normal reporting is not feasible (section III.C.)	1	1	1	8	8
4.102, 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
<i>Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products</i> ; Use of a targeted data collection tool to gather detailed case information specific to the product (section 9.4.)	1	23	23	1	23
<i>Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products</i> ; Expediently submit AERs of interest beyond minimum reporting requirements (section 9.4.)	12	55	660	0.1	66
<i>Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products</i> ; Summarize and assess AERs of interest at a frequency defined by FDA (e.g., in periodic safety reports or in some other form) (section 9.4.)	15	4	60	15	900
Total			2,156,757		3,629,691

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.

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
<i>Postmarket AER for Nonprescription Drug Products Guidance</i> ; (§ 329.100).	312	62.5224	19,507	8	156,056
<i>AERs During Pandemic Guidance</i> ; Continuity of operations planning (section III.B.).	100	1	100	50	5,000
<i>AERs During Pandemic Guidance</i> ; documenting conditions and resultant high absenteeism (section III.C.2).	350	1	350	8	2,800
<i>AERs During Pandemic Guidance</i> ; 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)	20
Total			1,549,327		24,627,828

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 2}

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

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

² Totals may not sum due to rounding.

Our estimates of the number of respondents and the total annual responses are based on reports submitted to the Agency. 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. This information collection and burden table includes 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.

We include burden attributable to provisions related to postmarketing safety reporting for combination products as outlined in 21 CFR part 4, subpart B. 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 applicant, 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>.

We are revising this information collection to account for burden that may be attributable to the best practice document entitled “Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products” (January 2024), available at <https://www.fda.gov/media/130216/download>. The best practice document describes enhanced pharmacovigilance activities which FDA may request of an applicant. For a specific product, these activities may include use of a targeted data collection tool to gather detailed case information regarding adverse experiences of interest, expeditious submission of adverse experiences of interest beyond minimum reporting requirements, and/or summarization and assessment of adverse experiences of interest at a frequency defined by FDA. Accordingly, we are revising this information collection to include burden in Table 1, rows 10 through 12, that we attribute to the enhanced pharmacovigilance

activities regarding a subset of adverse experience reports (adverse experiences of interest) which include submitting adverse experiences which would otherwise be submitted within a different timeframe, utilizing a targeted data collection tool for those adverse experiences and/or providing a summary and assessment of those adverse experiences for human drug and biological products. In addition, we revised Table 1, rows 3 and 4, to more accurately describe the two types of reports that are submitted under 314.80(c)(2). In doing so, we corrected an overreporting. We estimate no increase in the recordkeeping burden associated with enhanced pharmacovigilance activities because, although the reported contents or timeline may change slightly, the recordkeeping burden associated with the reporting vehicle remains unchanged.

We are also revising this information collection to account for the mandatory electronic submission of individual case safety reports (ICSRs) for drugs, biologics, and combination products using the data standards specified in the ICH E2B(R3) guideline when submitting ICSRs via the Electronic Submissions Gateway Next Generation (ESG NextGen). FDA adopted the ICH Implementation Guide (IG) for Electronic Transmission of Individual Case Safety Reports (ICSRs): E2B(R3) Data Elements and Message Specification (ICH ICSR IG) in February 2014. At present, FDA allows submitters to voluntarily use the E2B(R3) data standards in their ESG NextGen submissions. In January 2024, FDA began accepting electronic submissions of postmarketing ICSRs for human drug products, biological products, and drug- or biologic-led combination products submitted to AEMS via the ESG NextGen in electronic format using the ICH E2B(R3) data standards and announced that submitters could continue to submit using E2B(R2) standards for an additional two years during the E2B(R3) implementation period. On April 6, 2026, we announced that to facilitate implementation and enhance efficiency and alignment with internationally harmonized data standards, we are requiring that ICSRs submitted through ESG NextGen must be in the ICH E2B(R3) data standards beginning on October 1, 2026, unless earlier transition to ICH E2B(R3) data standards is needed to accommodate reporting requirements (see, for example, 21 CFR 314.81(b)(3)(v), added by the final rule entitled “Nonprescription Drug Product With an

Additional Condition for Nonprescription Use” (89 FR 105288, December 26, 2024)). See: <https://www.federalregister.gov/documents/2026/04/06/2026-06660/electronic-submission-of-postmarketing-individual-case-safety-reports-to-the-food-and-drug>.

The information provided by the ICH E2B(R3) standard is needed to improve the quality of data in ICSR submissions. We use the information to enable improved handling and analyses of ICSRs. Differences between ICH E2B(R2) and ICH E2B(R3) include, for example: new, changed, and expanded data elements; assessment of seriousness at the event level, rather than the case level; and embedding of attachments in the ICSR rather than providing separately.

We announced the adoption of the ICH E2B(R3) standard in February 2014 (79 FR 9908). In June of 2014, we amended our postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive (79 FR 33072). This revision reaffirmed our intention to continue to rely on ICH standards while also providing other options for providing electronic submissions to FDA. In this revision, we stated that it has been FDA’s practice to accept both the latest version of the ICH E2B standard in addition to the previous version to allow applicants reasonable time to transition to the updated ICH E2B standard. In this revision, we also stated that further changes to submission standards will be provided in guidance, as appropriate. In January 2024, we provided a transition period allowing voluntary use of the ICH E2B(R3) standard to minimize burden resulting from changes to the ICSR format. The purpose of the 2014 announcement and the 2024 transition period was to mitigate burden by allowing respondents time to implement changes to their submission systems. We note that many respondents that use the ESG NextGen are global industry participants and may have already adopted the ICH E2B(R3) standard for their submissions. Therefore, we believe that there is no change in the estimated burden associated with ICSR submissions over the ESG NextGen. Accordingly, we seek OMB approval of the mandatory implementation of the ICH E2B(R3) standard.

This information collection incorporates revisions to include the best practice document entitled “Best Practices for FDA Staff in the

Postmarketing Safety Surveillance of Human Drug and Biological Products” and its enhanced pharmacovigilance activities and to correct an unrelated overreporting error. We are otherwise retaining the burden hour estimates approved by OMB in this collection on July 31, 2025. As a result of this revision, the total burden hours of the information collection have decreased by 48,061,011 hours and increased by 23,743 responses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-09543 Filed 5-12-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0994]

Modified Risk Tobacco Product Application: Renewal Applications for VLN® King and VLN® Menthol King, Cigarette Products Submitted by 22nd Century Group Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability for public comment of modified risk tobacco product applications (MRTPAs) for renewal of existing MRTP orders for two cigarette products submitted by 22nd Century Group Inc.

DATES: Electronic or written comments on the application may be submitted beginning May 13, 2026. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments 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-0994 for “Modified Risk Tobacco Product Application: Renewal Applications for VLN® King and VLN® Menthol King, Cigarette Products Submitted by 22nd Century Group Inc.” 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read 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: Dhanya John or Justin Sherren, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA pursuant to section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in a MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make a MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on