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 61,615,010.1 hours and 2,546,310 responses as compared to the previous renewal. We invite comment on our assumptions.

Dated: September 18, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21675 Filed 9–20–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2020–N–2030 and FDA–2024–N–0972]**

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

| Title of collection | OMB control No. | Date approval expires |
|---|---|---|
| Applications for FDA Approval to Market a New Drug | 0910–0001 | 8/31/2025 |
| Regulations Under the Federal Import Milk Act | 0910–0212 | 8/31/2027 |

Dated: September 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21672 Filed 9–20–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2019–E–1081; FDA–2019–E–1082; FDA–2019–E–1083; FDA–2019–E–1084; FDA–2019–E–1085; and FDA–2019–E–1844]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; SYMDEKO

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SYMDEKO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 22, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 24, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

**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 November 22, 2024. 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 Nos. FDA–2019–E–1081; FDA–2019–E–1082; FDA–2019–E–1083; FDA–2019–E–1084; FDA–2019–E–1085; and FDA–2019–E–1844 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SYMDEKO.'' 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 § 10.20 (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:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51,