FDA's estimate of the number of respondents in tables 1 and 2 is based on data from the deeming rule Final Regulatory Impact Analysis,[1] which showed there are an estimated 362,273 retail establishments that currently sell tobacco products. The Agency reviewed these numbers again for this notice, and believe they are an accurate estimation. We assume that 75 percent of tobacco retailers already have some sort of age and identification verification training program in place. We expect that some of those retailer training programs already meet the elements in the guidance, some retailers would update their training program to meet the elements in the guidance, and other retailers would develop a training program for the first time. Thus, we estimate that two-thirds of tobacco retailers would develop a training program that meets the elements in the guidance (66 percent of 362,273 = 239,100; then annualized to 79,700).

We have adjusted our burden estimate and the number of respondents, which has resulted in a decrease to the currently approved burden and respondent count. This adjustment is based on available data estimating the number of retail establishments that sell tobacco products in the United States. Additionally, the burden chart was updated to reflect a change from an estimation over the course of 3 years to annualized burden.

Dated: November 1, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–24218 Filed 11–4–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0557]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance of Medical Devices

**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 December 7, 2022.

**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 0910–0449. Also include the FDA docket number found in brackets in the heading of this document.

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

### Postmarket Surveillance of Medical Devices—21 CFR Part 822

*OMB Control Number 0910–0449—Extension*

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers, so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with 21 CFR 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with 21 CFR 822.38. Respondents to this collection of information are those manufacturers that require PS of their products.

In the **Federal Register** of May 27, 2022 (87 FR 32169), 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]

| 21 CFR part/activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| §§ 822.9 and 822.10; PS submission | 5 | 1 | 5 | 120 | 600 |
| § 822.21; Changes to PS plan after approval | 9 | 1 | 9 | 40 | 360 |
| § 822.28; Changes to PS plan for a device that is no longer marketed | 1 | 1 | 1 | 8 | 8 |
| § 822.29; Waiver | 0 | 0 | 0 | 40 | 0 |
| § 822.30; Exemption request | 0 | 0 | 0 | 40 | 0 |
| § 822.38; Periodic reports | 17 | 3 | 51 | 40 | 2,040 |
| Total | | | | | 3,008 |

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

*Explanation of Reporting Burden Estimate:* The burden captured in table 1 is based on the data from FDA's internal tracking system. 21 CFR 822.26, 822.27, and 822.34 do not constitute information collection subject to review

[1] Deeming Tobacco Products to be Subject to the [Federal] Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Final Regulatory Impact Analysis, 2016 *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf.*

under the PRA because it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (see 5 CFR 1320.3(h)(1)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR part/activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| § 822.31; Manufacturer records | 5 | 1 | 5 | 20 | 100 |
| § 822.32; Investigator records | 15 | 1 | 15 | 5 | 75 |
| Total | | | | | 175 |

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

*Explanation of Recordkeeping Burden Estimate:* FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with PS.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Our estimated burden for the information collection reflects an overall decrease of 4,780 hours and a corresponding decrease of 145 responses. We believe these adjustments more accurately reflect the current number of requests associated with postmarket surveillance of medical devices.

Dated: November 1, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–24232 Filed 11–4–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–D–0776]**

### Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; 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 entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' The guidance document provides recommendations to sponsors interested in studying multiple versions of a cellular or gene therapy product in an early phase clinical trial for a single disease. Sponsors have expressed interest in gathering preliminary evidence of safety and activity using multiple versions of a cellular or gene therapy product in a single clinical trial, where each version of the product is distinct and is generally submitted to FDA in a separate investigational new drug application (IND). The guidance provides recommendations for conducting such studies, including how to organize and structure the INDs, submit new information, and report adverse events. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2021.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 7, 2022.

**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–0776 for ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' 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