## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2025–N–0706; FDA–2025–N–0373; FDA–2025–N–0734; FDA–2025–N–0195; FDA–2024–N–5579; FDA–2024–N–5944; FDA–2025–N–0339; FDA–2025–N–0418; FDA–2011–N–0179]**

### 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 Barrett, 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 |
|---|---|---|
| Environmental Impact Considerations | 0910–0322 | 11/30/2028 |
| Registration of Food Facilities | 0910–0502 | 11/30/2028 |
| Manufactured Food Regulatory Program Standards | 0910–0601 | 12/31/2028 |
| Production, Storage, and Transportation of Shell Eggs (preventing Salmonella Enteritidis (SE)) | 0910–0660 | 11/30/2028 |
| Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications | 0910–0750 | 11/30/2028 |
| Sanitary Transportation of Human and Animal Food | 0910–0773 | 11/30/2028 |
| Mitigation Strategies to Protect Food Against Intentional Adulteration | 0910–0812 | 11/30/2028 |
| Tropical Disease Priority Review Vouchers | 0910–0822 | 12/31/2028 |
| Adding Requirement to Submit Mail Tracking Number for Articles of Food Arriving by International Mail and Timeframe for Post-Refusal and Post-Hold Submissions | 0910–0923 | 12/31/2028 |

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–03774 Filed 2–24–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–D–0350]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Retailer Training Programs

**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 March 27, 2026.

**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 0910–0745. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Barrett, 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.

### Tobacco Retailer Training Programs

*OMB Control Number 0910–0745—Extension*

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387u). FDA intends to issue regulations establishing standards for approved tobacco retailer training programs under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)). In the interim, FDA published a guidance document entitled ''Tobacco Retailer Training Programs (Revised)'' (2018) that can be downloaded at *https://www.fda.gov/media/79013/download.* The guidance is intended to assist tobacco retailers to voluntarily implement effective training programs for employees.

The guidance discusses recommended elements that should be covered in a training program, such as: (1) Federal laws restricting the access to, and the advertising and promotion of, cigarettes, smokeless, and covered tobacco products; (2) the health and economic effects of tobacco use, especially when the tobacco use begins at a young age; (3) written company policies against sales to youth and other restrictions on the access to, and the advertising and promotion of, tobacco products; (4) identification of the tobacco products sold in the retail establishment that are subject to the Federal laws and regulations prohibiting their sale to underage persons; (5) age verification methods; (6) practical guidelines for refusing sales; and (7) testing to ensure that employees have the required

knowledge. The guidance recommends that retailers require current and new employees to take a written test prior to selling tobacco products and that refresher training be provided at least annually and more frequently as needed. The guidance recommends that retailers maintain certain written records documenting that all individual employees have been trained and that retailers retain these records for 4 years in order to be able to provide evidence of a training program during the 48-month time period covered by the civil money penalty schedules outlined in the law.

The guidance also recommends that retailers implement certain hiring and management practices as part of an effective retailer training program. The guidance suggests that applicants and current employees be notified both verbally and in writing of the importance of complying with laws prohibiting the sales of tobacco products to underage persons. In addition, FDA recommends that retailers implement an internal compliance check program and document the procedures and corrective actions for the program. In the **Federal Register** of August 22, 2025 (90 FR 41081), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments that were PRA related.

Both comments agreed that the proposed information collection is necessary and has practical utility. One of the comments explained that the retailer training program recommendations are linked to preventing youth access to tobacco products and improving compliance. The other comment explained that retailer training programs are a critical component of preventing youth access to tobacco products and ensuring compliance with federal law. FDA agrees with these comments.

One of the comments requested that FDA provide materials to the public for the development of retail training programs, such as retailer checklists covering the guidance recommendations, model nonbinding templates for written policies and standard operating procedures, and minimal data fields for employee records, to improve uniformity. The same comment suggested that FDA could leverage specific automation and information technology tools to minimize the burden on respondents. FDA disagrees with the comment. The guidance provides recommendations for elements to be included in retailer training programs and recommended hiring and management practices to assist retailers in complying with Federal tobacco laws and regulations. Retailers who want to train employees about Federal requirements may incorporate the elements described in the guidance into their existing training programs, as appropriate. The guidance also encourages the inclusion of training related to specific age verification techniques using point of sale scanning systems and electronic age verification devices. Additionally, FDA has provided several resources, such as webinars and downloadable materials through FDA's ''This is Our Watch'' Program, to assist retailers in complying with the requirements under the law.

Both comments suggested that FDA approve or otherwise explicitly recognize that certain existing retailer training programs and certifications satisfy recommended elements of the guidance. The comments suggest that FDA approval or recognition of these programs and certifications will improve the quality and usefulness of the collected information. FDA disagrees with this comment. The Tobacco Control Act does not require retailers to implement retailer training programs, and retailers are under no obligation to submit their training programs for FDA review because this is a voluntary program. Additionally, the guidance establishes non-binding recommendations for the elements that should be included in a retailer training program, it does not establish requirements. To do so, FDA must first promulgate regulations establishing standards for approved retailer training programs. FDA has not yet promulgated these regulations, and currently FDA is not in a position to recognize any program or certification as an approved retailer training program.

With respect to the burden estimates, one comment indicated that FDA may have overestimated the number of retailers that would need to develop a training program as many may already have training programs in place or may adopt existing programs. The same comment suggested that FDA may have underestimated the burden per recordkeeper in Tables 1 and 2, but its estimates may be reasonable if FDA evaluates the burden by retailer size and type. The other comment indicated that FDA's burden estimates are likely reasonable. FDA agrees that it may have overestimated the number of retailers that would develop new retailer training programs and has adjusted the number of recordkeepers in Table 1 as described below. FDA is not adjusting the average burden values, as both commentors agree that those estimates could be reasonable. While one comment noted that the burden may change per size and sophistication of the retailer, the recommendations of the guidance are not retail size or type specific. Additionally, FDA considered the availability of online support resources provided by FDA to assist all retail establishments in developing training programs and internal compliance check programs in determining the average burden per recordkeeper.

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

TABLE 1—ESTIMATED ONE TIME ANNUAL RECORDREPORTING BURDEN[1]

| Activity (guidance section IV) | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper in hours | Total hours |
|---|---|---|---|---|---|
| Develop training program | 18,969 | 1 | 18,969 | 16 | 303,504 |
| Develop written policy against sales to minors and employee acknowledgement | 18,969 | 1 | 18,969 | 1 | 18,969 |
| Develop internal compliance check program | 18,969 | 1 | 18,969 | 8 | 151,752 |
| Total | | 3 | | 25 | 474,225 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity (guidance section IV) | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper in hours | Total hours |
|---|---|---|---|---|---|
| Training program | 237,113 | 4 | 948,452 | 0.25 (15 minutes) | 237,113 |
| Written policy against sales to minors and employee acknowledgement. | 237,113 | 4 | 948,452 | 0.10 (6 minutes) | 94,845 |
| Internal compliance check program | 237,113 | 2 | 474,226 | 0.5 (30 minutes) | 237,113 |
| Total | | | | | 569,071 |

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

As explained above, FDA is adjusting its burden calculations based on more recently available retailer data. FDA's estimate of the number of respondents in tables 1 and 2 is based on 2022 data from the Census Bureau's Economic Census,[1] Statistics of U.S. Businesses (SUSB),[2] and Business Dynamics Statistics (BDS).[3]

We use SUSB and Economic Census data to estimate the counts of retail establishments that sell tobacco products,[4] resulting in a count of 237,113 total tobacco product retail establishments who keep records of training programs, written policies, and internal compliance check programs (Table 2) annually. From the 2022 Business Dynamics Statistics, we calculate establishment entry and exit rate of approximately 8 percent, on average, for NAICS industry codes 4451 (Grocery and Convenience Retailers) and 4471 (Gasoline Stations)—these two categories represent more than 60% of our estimated total count of tobacco product retail establishments. In Table 1, we estimate 18,969 tobacco retail establishments (= 237,113 total establishments × 8 percent) may newly develop retailer training programs, written policies, and internal compliance check programs annually.

In Table 1, FDA estimates that developing a training program will require 16 hours, creating a written procedure may take 1 hour, and developing an internal compliance check program will require 8 hours for a total of 25 hours per respondent.

For Table 2, the guidance recommends retailers periodically review and update their established training program, written policies, and internal compliance checks. Annually, we assume training programs and written policies will be reviewed and updated quarterly and therefore estimate 4 records per recordkeeper, taking 21 minutes per quarter (= 15 minutes + 6 minutes). Following the guidance, we assume retailers will conduct internal compliance checks every 6 months and therefore estimate 2 records per recordkeeper annually, taking 30 minutes per record.

FDA has updated the counts of tobacco product retail establishments in Table 1 and Table 2 using more recent data from Census Bureau on the number of retail establishments that sell tobacco products and retail establishment entry and exit rates. FDA considered the availability of online support resources provided by FDA to assist retail establishments in developing training programs and internal compliance check programs, and believe that the average burden values are appropriate

Since publication of the 60-day notice, FDA has updated the estimated annual burden for this information collection in response to a public comment received during the 60-day comment period. Based on further review of the assumptions used to calculate burden, the total estimated annual hours have changed from 2,183,780 hours to 1,043,296 hours, an overall decrease of 1,140,484 hours.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–03771 Filed 2–24–26; 8:45 am]

**BILLING CODE 4164–01–P**

[1] *www.census.gov/programs-surveys/economic-census/year/2022/news-updates/ecdata-releases.html.* (EC2200NAPCSINDPRD Industry by Product and EC2200NAPCSPRDIND

[2] *www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html.*

[3] *www.census.gov/data/data-tools/bds-explorer.html.*

[4] NAICS codes—44511 (Supermarkets and Other Grocery (except Convenience) Stores), 44512 (Convenience Stores), 44530 (Beer, Wine, and Liquor Stores), 44611 (Pharmacies and Drug Stores), 44711 (Gasoline Stations with Convenience Stores), 44719 (Other Gasoline Stations), 452311 (Warehouse Clubs and Supercenters), 452319 (All Other General Merchandise Stores), and 453991 (Tobacco Stores). Economic Census data were used to determine the percent of establishments within each NAICS code that sell tobacco products.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection: 30-Day Comment Request; The Clinical Trials Reporting Program (CTRP) Database (NCI)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received by March 27, 2026.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Melissa Park, PRA Liaison, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2E196, Bethesda, MD 20892 or call non-toll-free number (240) 276–5717 or email your request, including your address to: *melissa.park@nih.gov.*

Formal requests for additional plans and instruments must be requested in writing.