

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Total .....	.....	.....	.....	.....	90

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

Our estimate for the information collection reflects an overall increase of burden. This increase corresponds to an increase in submissions we have received over the last few years.

Dated: November 6, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–24780 Filed 11–14–19; 8:45 am]

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**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; Guidance for Tobacco Retailers on 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:** Fax written comments on the collection of information by December 16, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0745. 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](mailto: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.

**Guidance for Tobacco Retailers on Tobacco Retailer Training Programs**

*OMB Control Number 0910–0745—Extension*

**I. Background**

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) does not require retailers to implement retailer training programs. However, the statute does provide for lesser civil money penalties for violations of access, advertising, and promotion restrictions of regulations issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by FDA for such programs. FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, the guidance is intended to assist tobacco retailers in implementing 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 minors 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 prohibiting their sale to persons under the age of 18; (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 in section 103(q)(2)(A) of the Tobacco Control Act.

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 persons under the age of 18. 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 June 17, 2019 (84 FR 28059), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related.

The comment suggested that FDA should adjust the burden calculation for two areas, develop training programs and review and updating training programs. The comment suggested that it would reasonably take 1000 hours to develop a training program. FDA disagrees with this comment and does not intend to adjust the burden calculations for these areas. FDA has not made significant changes to this guidance and expects that many 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 a smaller number of other retailers would develop a training program for the first time. FDA has not received any comments from affected retailers regarding the time needed to develop retailer training programs, or that the burden calculation was insufficient. 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. FDA

estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Develop training program .....	273,900	1	273,900	16	4,382,400
Develop written policy against sales to minors and employee acknowledgement .....	273,900	1	273,900	1	273,900
Develop internal compliance check program .....	273,900	1	273,900	8	2,191,200
<b>Total .....</b>					<b>6,847,500</b>

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Training program .....	273,900	4	1,095,600	0.25 (15 minutes)	273,900
Written policy against sales to minors and employee acknowledgement .....	273,900	4	1,095,600	0.10 (6 minutes) ..	109,560
Internal compliance check program .....	273,900	2	547,800	0.5 (30 minutes) ..	273,900
<b>Total .....</b>					<b>657,360</b>

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

FDA's estimate of the number of respondents in tables 1 and 2 is based on data reported to the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration. According to the fiscal year 2009 Annual Synar Report, there are 372,677 total retail tobacco outlets in the 50 States, District of Columbia, and 8 U.S. territories that are accessible to youth (meaning that there is no State law restricting access to these outlets to individuals older than age 18). Inflating this number by about 10 percent to account for outlets in States that sell tobacco but are, by law, inaccessible to minors, results in an estimated total number of tobacco outlets of 410,000. We assume that 75 percent of tobacco retailers already have some sort of training program for age and identification verification. 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% of 410,000 = 270,600).

FDA estimates that the total burden for this collection will be 7,504,860 hours (6,847,500 reporting + 657,360 recordkeeping).

We also estimate that there are approximately 5,000 to 10,000 vape shops; we assume that 66 percent of them, or 3,300 (66% × 5,000) of the low estimate, currently engage in retailing activities (Ref. 1).

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

**II. Reference**

The following reference is on display with the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at <https://www.regulations.gov> as this reference is copyright protected. It may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Burke, D., "Trends & Insights in the Nicotine Delivery Category." Management Science Associates, Inc. Presentation at NATO Show, April 23, 2015.

Dated: November 6, 2019.  
**Lowell J. Schiller**,  
*Principal Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-D-0530]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Q-Submission Program for 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:** Fax written comments on the collection of information by December 16, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0756. Also include the FDA docket number found