Estimated Total Annual Burden Hours: 20,552.

Dated: July 25, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–18177 Filed 7–29–16; 8:45 am]

BILLING CODE 4154–01–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; Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 August 31, 2016.

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.* 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20851, *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

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 the 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 and smokeless 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; (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 and that they should be required to sign an acknowledgement stating that they have read and understand the information. In addition, FDA recommends that retailers implement an internal compliance check program and document the procedures and corrective actions for the program.

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 (SAMHSA). 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 percent of 410,000 = 270,600).

The Tobacco Control Act gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product as subject to FDA regulatory authority (''deeming'') (section 901(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). On May 10, 2016, FDA issued the deeming rule, extending FDA's tobacco product authority to other tobacco products (81 FR 28973). In the **Federal Register** of February, 26, 2016 (81 FR 9862), FDA published the 60-day notice requesting public comment on the proposed collection of information. Since FDA published the 60-day notice before the deeming rule, FDA has adjusted the burdens in this information collection to reflect the expected increase in the number of affected retail establishments based on the publication of the deeming rule, as detailed below. 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) Two PRA related comments were received in response to the 60-day notice.

The two comments both identified additional training options that could be used to provide further educational opportunities for tobacco retailers. These comments primarily relate more to the content and method of a retailer training program rather than the proposed collection of information associated with the current guidance document. At the same time, one comment was supportive of the information collection activities associated with the current guidance document. FDA is supportive of training programs that assist retailers in complying with the tobacco control laws.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

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
Total					6,847,500

[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	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	.25 (15 minutes)	279,300
Written policy against sales to minors and employee acknowledgement.	273,900	4	1,095,600	.10 (6 minutes)	109,560
Internal compliance check program	273,900	2	547,800	.5 (30 minutes)	279,300
Total					668,160

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

FDA estimates that the total burden for this collection will be 7,515,660 hours (6,847,500 reporting + 668,160 recordkeeping).

Reference

1. Burke, Don, ''Trends & Insights in the Nicotine Delivery Category.'' Management Science Associates, Inc. Presentation at NATO Show, April 23, 2015. Accessed June 2015.

Dated: July 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18092 Filed 7–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1428]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Electronic Drug Product Reporting of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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 August 31, 2016.

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.* All comments should be identified with the title. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown Street, North Bethesda, MD 20852, *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 Industry: Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability—OMB Control Number 0910—(NEW)

On November 27, 2013, the President signed the Drug Quality and Security Act (DQSA) into law (Pub. L. 113–54).