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 [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	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
Total					657,360

[1] 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.

[FR Doc. 2019–24785 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

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.* All comments should be identified with the OMB control number 0910–0756. 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.

Q-Submission Program for Medical Devices

OMB Control Number 0910–0756—Extension

The guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (*https://www.fda.gov/media/114034/download*) provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with FDA regarding certain potential or planned medical device submissions reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submissions Types and other uses of the Q-Submission Program.

For clarity and consistency with the guidance that describes the program, we are requesting that the title of the information collection request, OMB control number 0910–0756, be changed to ''Q-Submission Program for Medical Devices.''

In the **Federal Register** of August 13, 2019 (84 FR 40069), 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]

FDA Center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	3,502	1	3,502	137	479,774
CBER	91	1	91	137	12,467
Total					492,241

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

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 3,593 submissions is based on experienced recent trends. FDA's administrative and technical staffs, who are familiar with Q-Submissions, estimate that an average of 137 hours is required to prepare a Q-Submission.

Our estimated burden for the information collection reflects an overall increase of 143,713 hours. We attribute this adjustment to an increase in the number of submissions we received based on FY18 data.

Dated: November 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24803 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0796]

Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on communication studies involving medical devices and radiation-emitting products regulated by FDA. This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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