TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR part 1; subpart M	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 1.624(c)	25	1	25	8	200
§ 1.657(d)	208	1	208	8	1,664
§ 1.652	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.653(b)(2)	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.656(c)	208	0.25	52	1	52
Total Annual Recordkeeping Burden					25,193

[1] There are no capital costs or operating and maintenance costs associated with annual recordkeeping burden.
[2] Initial burden for an AB seeking recognition or a CB seeking accreditation.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 1; subpart M	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§ 1.630 [2]	7	1	7	80	560
§ 1.670 [2]	1	1	1	80	80
§ 1.634	25	1	25	8	200
§ 1.672	1	1	1	10	10
§ 1.623(a)	25	9	225	0.25 (15 minutes)	56
§ 1.623(b)	25	1	25	0.25 (15 minutes)	6
§ 1.653(b)(1)	208	48.5	10,088	0.25 (15 minutes)	2,522
§ 1.656(a) [3]	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) [4]	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) [5]	1	55.4	55	0.25 (15 minutes)	14
§ 1.656(b) [6]	207	1	207	0.25 (15 minutes)	52
§ 1.656(b) [7]	1	1	1	0.25 (15 minutes)	1
§ 1.656(c)	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) [8]	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) [9]	207	0.25	52	0.25 (15 minutes)	13
Total Annual Reporting Burden					8,560

[1] There are no capital costs or operating and maintenance costs associated with annual reporting.
[2] Initial burden for an AB seeking recognition or a CB seeking accreditation.
[3] Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.
[4] Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to FDA.
[5] Annual reporting of regulatory audit reports by directly accredited CBs to FDA.
[6] Annual reporting of self-assessment by accredited CBs to their recognized ABs.
[7] Annual reporting of self-assessment by directly-accredited CBs to FDA.
[8] Annual reporting of serious risk to public health by CBs accredited under the third-party program to eligible entities.
[9] Annual reporting of serious risk to public health by accredited CBs to their recognized ABs.

The total annual recordkeeping burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 25,193 hours (see table 1). We assume that all ABs that apply for recognition in the program become recognized and all CBs that apply for accreditation are accredited. The total annual reporting burden by 25 recognized ABs and 208 CBs accredited under the program is estimated at 8,560 hours (see table 2). These estimates reflect a correction to the estimates published in the last 60-day notice, which did not include estimates for the initial burden needed to apply for entry into the program.

We have adjusted our burden estimate since the last OMB approval to reflect the decrease of burden associated with one-time recordkeeping and reporting activities and have revised our estimate to reflect the initial burden for new ABs seeking recognition and new CBs seeking accreditation. The adjustment resulted in decreases of 7,421 responses and 41,069 total burden hours.

Dated: June 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12703 Filed 6–14–19; 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; Proposed Collection; 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 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 the information collection aspects of the Guidance for Tobacco Retailers on Tobacco Retailer Training Programs.

DATES: Submit either electronic or written comments on the collection of information by August 16, 2019.

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 August 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 16, 2019. 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 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–2010–D–0350 for ''Guidance for Tobacco Retailers on Tobacco Retailer Training Programs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- 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 claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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.

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 percent 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: June 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12677 Filed 6–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2312]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Allergenic Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Allergenic Products Advisory Committee (APAC) for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the APAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by July 17, 2019, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by July 17, 2019.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.* Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, Fax: 301–595–1307, email: *Serina.Hunter-Thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. Allergenic Products Advisory Committee

The committee reviews and evaluates data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner) of its findings regarding the affirmation or revocation of biological product licenses; on the safety, effectiveness, and labeling of the products; on clinical and laboratory studies of such products; on amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products; and on the quality and relevance of FDA's research programs which provide the scientific support for regulating these agents.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12678 Filed 6–14–19; 8:45 am]

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