burden of approximately 1 hour, taking into account that some respondents may not have readily available Internet access. Thus, the total annual burden for cancelling Shell Egg Producer registrations is estimated to be 15 hours (15 cancellations × 1 hour).

Dated: March 20, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07032 Filed 3–26–13; 8:45 am]

BILLING CODE 4160–01–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 Industry 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 April 26, 2013.

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–NEW and title ''Guidance for Industry on Tobacco Retailer Training Programs.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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 on Tobacco Retailer Training Programs—(OMB Control Number 0910–NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act grants FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The Tobacco Control Act provides for lower civil money penalties for violations of sale and distribution, including youth access, and advertising and promotion restrictions issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C 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 (section 103(q)(2) of the Tobacco Control Act). 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 training programs for employees.

The guidance discusses the elements that should be covered in a training program, such as: (1) Federal laws restricting the sale and distribution, including youth 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 the sale of cigarettes and smokeless tobacco to minors; (4) identification of the cigarettes and smokeless tobacco sold in the retail establishment that are subject to the Federal laws prohibiting their sale to persons under the age of 18; and (5) age verification methods.

The guidance recommends that retailers train current employees as soon as practicable and that new employees be trained prior to selling cigarettes and smokeless tobacco. Refresher training should be provided at least annually and more frequently, as needed. In addition, the guidance recommends that retailers review and update their training program, as needed, and take appropriate corrective action after any violation of the regulations restricting sale and distribution, including youth access, and advertising and promotion of cigarettes and smokeless tobacco. The guidance recommends that retailers document any modifications to the training program following such a review.

The guidance recommends that retailers maintain certain 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 a retailer training program.

In the **Federal Register** of July 16, 2010 (75 FR 41498), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received seven comments in response to the notice, with four comments on the information collection. In the **Federal Register** of November 25, 2011 (76 FR 72710), FDA republished notice of the proposed collection of information in order to comply with section 3506(c)(2)(A) of the Paperwork Reduction Act. FDA received two comments that were beyond the scope of the information request (e.g., raising fines will be more successful than retailer training, support for educating retail employees about the negative effects of using tobacco products). Comments relevant to the information request are addressed in this document.

(Comment 1) Several comments stated that it would be burdensome and costly to keep training records for 4 years due to the high turnover in the retail industry.

(Response) The Tobacco Control Act does not require retailers to implement retailer training programs. However, it provides for two schedules of civil money penalties for violations of restrictions issued under section 906(d) of the FD&C Act pertaining to the sale and distribution of tobacco products, including access, advertising, and promotion restrictions—a schedule of lower penalties for retailers who have implemented a training program that complies with the standards set by FDA and a schedule of higher penalties for those who have not. Until FDA issues regulations establishing standards for approved retailer training programs, the Agency intends to seek penalties within the range provided by section 103(q)(2)(A)(i) of the Tobacco Control Act (for retailers with an approved retailer training program) whether or not the retailer has implemented a training program. FDA may consider further reducing the civil money penalty for retailers who have implemented a

training program. Retailers who wish to implement training programs should retain their records for 4 years 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.

(Comment 2) Several comments suggested that retailers be allowed to keep electronic and/or written records of their training programs.

(Response) We agree. The guidance provides that retailers may determine the format of the records to be maintained (e.g., paper, electronic).

(Comment 3) Several comments suggested that, due to the high employee turnover in the retail industry, it would be burdensome for retailers to have job applicants sign an acknowledgment stating that they have read and understand the importance of complying with laws prohibiting the sale of cigarettes and smokeless tobacco.

(Response) We agree with these comments and revised the guidance accordingly. However, we do not believe these changes will affect the burden for this information collection. In light of the comments' statements about the high turnover in the retail industry, it is possible that we underestimated the annual frequency for this recordkeeping. Therefore, we invite comments on the burden for employee acknowledgments to assist FDA in determining more accurate burden estimates in the future.

(Comment 4) One comment suggested that retailers who receive a Complaint for Civil Money Penalties from FDA and who seek to have their penalty reduced because they have a training program should show that all staff involved in the violation had received the initial training and that remedial action was taken after the violation.

(Response) We agree with this comment and revised the guidance to provide recommendations regarding when retailers should review and update their training program. Table 2 of this document includes our burden estimates for reviewing and updating retailer training programs. We estimate that retailers will review and update their training programs, on average, once a year. We invite comment on this burden estimate to assist FDA in determining a more accurate burden estimate in the future.

As discussed in this document, FDA has adjusted the burden for this information collection based on public comments received for 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 on a one-time basis that meets the elements in the guidance (66 percent of 410,000 = 270,600).

With regard to reporting burden, we expect that all 270,600 retailers would develop a training program on a one-time basis. Table 1 estimates the one-time burden for retailers. In addition, we expect that all 270,600 retailers would maintain records. Table 2 estimates the recordkeeping burden for retailers.

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

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Develop training program	270,600	1	270,600	16	4,329,600
Develop written policy against sales to minors & employee acknowledgment	270,600	1	270,600	1	270,600
Develop internal compliance check program	270,600	1	270,600	8	2,164,800
Total					6,765,000

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

[2] Because the reporting burden in this table is for one-time activities only, the annualized burden for this table is estimated to be 2,255,000 (6,765,000 one-time burden hours divided by 3 years expected OMB approval).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Training program	270,600	4	1,082,400	0.25 (15 minutes)	270,600
Review and update training program	270,600	1	270,600	0.5 (30 minutes)	135,300
Written policy against sales to minors & employee acknowledgment	270,600	4	1,082,400	0.10 (6 minutes)	108,240
Internal compliance check program	270,600	2	541,200	0.5 (30 minutes)	270,600

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Total					784,740

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

Dated: *March 21, 2013.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06982 Filed 3–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0257]

Summit on Color in Medical Imaging; Cosponsored Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of cosponsored public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) and cosponsor International Color Consortium (ICC) are announcing the following public workshop entitled ''Summit on Color in Medical Imaging: An International Workshop on the Technical Framework for Consistency and Interoperability Approaches for Dealing with Color in Medical Images.'' The purpose of the workshop is to bring together key stakeholders to clearly identify areas of need, investigate solutions, and propose best-practice approaches. The recommendations of the summit might include the creation of a technical special interest group either as part of the ICC or in some other forum and the establishment of best-practice guidelines for industry.

DATES: *Date and Time:* The workshop will be held on May 8 and 9, 2013, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact: Aldo Badano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3116, Silver Spring, MD 20993–0002, 301–796–2534, *Aldo.Badano@fda.hhs.gov.*

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on April 26, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Susan Monahan at 301–796–5661 to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (*Susan.Monahan@fda.hhs.gov* or 301–796–5661) no later than April 26, 2013.

Streaming Webcast of the Public Workshop: This workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on April 26, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after May 2, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

Requests for Oral Presentations: This workshop includes a public comment session. If you wish to present during a public comment session, you must indicate this at the time of registration. You shall also submit a title and short abstract of your comments to Veronika Lovell at *Veronika.lovell@sunchemical.com.*

Comments: FDA is holding this public workshop to obtain information on the topics identified in Section II. No commercial or promotional material will be permitted to be presented or distributed at the workshop. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is May 31, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written