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

21 CFR Section and/or section of FD&C act	FDA form No.	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
New Facility Registration Subtotal						207,026
Previously Registered Facilities						
Updates under § 1.234 and section 415 of the FD&C Act.	FDA 3537	118,530	1	118,530	1.2	142,236
Cancellations under § 1.235	FDA 3537a	6,390	1	6,390	1	6,390
Biennial renewal of registration required by section 415 of the FD&C Act.	FDA 3537	224,930	1	224,930	0.5 (30 minutes)	112,465
Updates, Cancellations or Biennial Renewals Subtotal.						261,091
Total Hours Annually						468,117

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3537" refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at *http://www.access.fda.gov.*

This estimate is based on FDA's experience and the average number of new facility registrations, updates and cancellations received in the past 3 years. FDA received 12,011 new domestic facility registrations during 2010; 10,646 during 2011; and 10,584 during 2012. Based on this experience, FDA estimates the annual number of new domestic facility registrations will be 11,080. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 2.5 hours per average domestic facility registration. We estimate that the FSMA-required additional information for new facility registrations will require an additional 12 minutes (0.2 hour) per response for domestic facilities. The average domestic facility burden hour estimate of 2.7 hours takes into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new domestic facility registrations is estimated to be 29,916 hours (11,080 x 2.7 hours).

FDA received 20,598 new foreign facility registrations during 2010; 20,009 during 2011; and 19,092 during 2012. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 19,900. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 8.5 hours per average foreign facility registration. We estimate that the FSMA-required additional information for new facility registrations will require an additional 24 minutes (0.4 hour) per response for foreign facilities. The average foreign facility burden hour estimate of 8.9 hours includes an estimate of the additional burden on a foreign facility to obtain a U.S. agent, and takes into account that for some foreign facilities the respondent completing the registration may not be fluent in English and/or not have readily available Internet access. Thus, the total annual burden for new foreign facility registrations is estimated to be 177,110 hours (19,900 × 8.9 hours).

Based on its experience, FDA estimates that the average annual number of updates to facility registrations will remain unchanged at 118,530 updates annually over the next 3 years. FDA also estimates that updating a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. We estimate that the FSMA-required additional information for updates will require an additional 12 minutes (0.2 hour) per response. Thus, the total annual burden of submitting updates to facility registrations is estimated to be 142,236 hours (118,530 x 1.2 hours).

Based on its experience, FDA estimates that the average annual number of cancellations of facility registrations will remain unchanged at 6,390 cancellations annually over the next 3 years. FDA also estimates that cancelling a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. FSMA did not change the required information for cancellations. Thus, the total annual burden for cancelling registrations is estimated to be 6,390 hours.

We estimate that the new biennial registration required by FSMA, which will require the submission of certain new data elements and the verification and possible updating of other information rather than re-entering all information, will require 30 minutes (0.5 hour) per response, including time for the new FSMA-required information. FDA estimates that, on an annualized basis, the number of biennial registrations submitted over the next 3 years will be 224,930. This estimate is based on the number of currently registered firms (449,860) divided by 2. Thus, the total annual burden for biennial registration is estimated to be 112,465 hours (224,930 × 0.5 hours).

Dated: March 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–07029 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–0297]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prevention of Salmonella Enteritidis in Shell Eggs During Production—Recordkeeping and Registration Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the

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 provisions of FDA's recordkeeping and registration requirements for shell egg producers.

DATES: Submit either electronic or written comments on the collection of information by May 28, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5733, *domini.bean@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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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.

Prevention of *Salmonella* Enteritidis in Shell Eggs During Production—Recordkeeping and Registration Provisions—21 CFR 118.10 and 118.11 (OMB Control Number 0910–0660)—Extension

Shell eggs contaminated with *Salmonella* Enteritidis (SE) are responsible for more than 140,000 illnesses per year. The Public Health Service Act (PHS Act) authorizes the Secretary of Health and Human Services to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

On July 9, 2009, FDA published in the **Federal Register** a final rule that established a regulation at part 118 (21 CFR part 118) entitled ''Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation'' (74 FR 33030) (the Shell Eggs final rule). Part 118 requires shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule and to register with FDA. As described in more detail with regard to each information collection provision of part 118, each farm site with 3,000 or more egg-laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all of their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Section 118.10 of FDA's regulations requires recordkeeping for all measures the farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are maintained on file at each farm site and examined there periodically by FDA inspectors.

Section 118.10 also requires each farm site with 3,000 or more egg-laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan. Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 of FDA's regulations requires that each farm covered by § 118.1(a) register with FDA using Form FDA 3733. The term ''Form FDA 3733'' refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *http://www.access.fda.gov.* The Agency strongly encourages electronic registration because it is faster and more convenient. The system the Agency has developed can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer will receive confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations will also be accepted. Form FDA 3733 is available for download for registration for submission by mail or CD–ROM (see *http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ShellEggProducerRegistration/ucm217952.htm#cdrom*).

Recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for us to be able to determine compliance. Information provided under these regulations helps us to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support our enforcement activities.

Description of Respondents: Respondents to this information collection include farm sites with 3,000 or more egg-laying hens that sell raw

eggs to the table egg market, other than directly to the consumer.

We estimate the burden of this collection of information as follows:

Recordkeeping Burden

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Description and 21 CFR section	No. of record-keepers [2]	No. of records per record-keeper	Total annual records	Average burden per recordkeeping	Total hours
Refrigeration Records, § 118.10(a)(3)(iv)	2,600	52	135,200	0.5	67,600
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) to (a)(3)(viii) (positive) [3]	343	52	17,836	0.5	8,918
Egg Testing, § 118.10(a)(3)(vii)	331	7	2,317	8.3	19,231
Environmental Testing, § 118.10(a)(3)(v) [3]	6,308	23	145,084	0.25	36,271
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) to (a)(3)(viii) (negative) [3]	5,965	1	5,965	0.5	2,983
Prevention Plan Review and Modifications, § 118.10(a)(4)	331	1	331	10	3,310
Chick and Pullet Procurement Records, § 118.10(a)(2)	4,731	1	4,731	0.5	2,366
Rodent and Other Pest Control, § 118.10(a)(3)(ii), and Biosecurity Records, § 118.10(a)(3)(i)	9,462	52	492,024	0.5	246,012
Prevention Plan Design, § 118.10(a)(1)	150	1	150	20	3,000
Cleaning and Disinfection Records, § 118.10(a)(3)(iii)	331	1	331	0.5	166
Total hours					389,857

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Some records are kept on a by-farm basis and others are kept on a by-house basis.
[3] Calculations include requirements for pullet and layer houses.

FDA is retaining most of the estimates published in the Shell Eggs final rule with regard to the estimated number of respondents and the average burden per recordkeeping (74 FR 33030 at 33089 to 33091). FDA bases the remaining recordkeeping burden estimates and the reporting burden estimates on its experience implementing the final rule and the number of registrations and cancellations received in the past 3 years.

The number of recordkeepers estimated in column 2 of table 1 and all other estimates discussed in this section are drawn from estimates of the total number of layer and pullet houses affected by the Shell Eggs final rule (74 FR 33030 at 33078 to 33080). In the final rule, we assumed that those farms that were operating according to recognized industry or State quality assurance plans were already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore would not experience additional costs to comply with recordkeeping provisions. We found that 59 percent of farms with more than 50,000 layers were members of State or industry quality assurance plans. Fewer than 8 percent of farms with fewer than 50,000 layers were members of quality assurance plans. Thus, we estimated the number of layer farms incurring a new recordkeeping burden because of the Shell Eggs final rule to be 2,600, and the number of houses affected to be 4,731. A detailed breakdown of this estimation is shown in table 29 of the Shell Eggs final rule (74 FR 33030 at 33078).

Prevention plan design (§ 118.10(a)(1)) records will be kept on a per farm basis but because the Shell Eggs final rule has been fully implemented, FDA assumes that new prevention plan design will only be undertaken by new entrants to the industry. Refrigeration records (§ 118.10(a)(3)(iv)) will also be kept on a per farm basis so the estimated number of recordkeepers for this provision is 2,600.

Records of chick and pullet procurement (§ 118.10(a)(2)), rodent and other pest control (§ 118.10(a)(3)(ii)), and biosecurity (§ 118.10(a)(3)(i)) will be kept on a per house basis, so the estimated number of recordkeepers for these provisions is 4,731.

Records of cleaning and disinfection (§ 118.10(a)(3)(iii)) will also be kept on a per house basis, but will only need to be kept in the event that a layer house tests environmentally positive for SE. Prevention plan review and modifications (§ 118.10(a)(4)) will also need to be performed every time a house tests positive. As discussed in section V.F of the Shell Eggs final rule (74 FR 33030 at 33078 to 33080), FDA estimated that 7.0 percent will test positive after the provisions of the rule took effect. Therefore, the number of recordkeepers for these provisions is estimated to be 331 (4,731 houses × 0.070) annually.

Records of testing, diversion, and treatment (118.10(a)(3)(v) to (a)(3)(viii)) will be kept on a per house basis and will include records on flocks from pullet houses. In the Shell Eggs final rule, FDA estimated that there are one third as many pullet houses as there are layer houses. Therefore the total number of recordkeepers for these provisions is 6,308 (4,731 + (4,731/3)). The number of annual records kept depends on whether or not houses test positive for SE. Annually, 343 layer and pullet houses ((4,731 layer houses × 0.070) + ((4731/3 pullet houses) × 0.0075)) are expected to test positive and 5,965 are expected to test negative ((4,731 layer houses × 0.930) + ((4731/3 pullet houses) × 0.9925)).

We assume that refrigeration records will be kept on a weekly basis on a per farm basis under § 118.10(a)(3)(iv)). We estimate that 2,600 recordkeepers will maintain 52 records each for a total of 135,200 records and that it will take approximately 0.5 hour per recordkeeping. Thus, the total annual burden for refrigeration records is estimated to be 67,600 hours (135,200 × 0.5 hour).

We assume that records of testing, diversion, and treatment under § 118.10(a)(3)(v) to (a)(3)(viii)) will be kept weekly in the event a layer house tests environmentally positive for SE. We estimate that 343 layer and pullet houses will test positive and thus 343 recordkeepers will maintain 52 records each for a total of 17,836 records and that it will take approximately 0.5 hour per recordkeeping. Thus, the total annual burden for testing, diversion, and treatment records in the event of a positive test result is estimated to be 8,918 hours (17,836 × 0.5 hour).

Given a positive environmental test for SE., we estimate the weighted average number of egg tests per house

under § 118.10(a)(3)(vii)) to be 7. We estimate that 331 recordkeepers will maintain 7 records each for a total of 2,317 records and that it will take approximately 8.3 hours per recordkeeping. Thus, the total annual burden for egg testing is estimated to be 19,231 hours (2,317 × 8.3 hours).

FDA estimates that all 1,577 pullet and 4,731 layer houses not currently testing (6,308 recordkeepers) will incur the burden of a single environmental test annually under § 118.10(a)(3)(v)). The number of samples taken during the test depends on whether a farm employs the row based method (an average of 12 samples per house) or the random sampling method (32 samples per house). For the purposes of this analysis we estimate that roughly 50 percent of the houses affected will employ a row based method and 50 percent will employ a random sampling method, implying an average of 23 samples per house. Thus, we estimate that 6,308 recordkeepers will take 23 samples each for a total of 145,084 samples. The time burden of sampling is estimated on a per swab sample basis. We estimate that it will take approximately 15 minutes to collect and pack each sample. Thus, the total annual burden for environmental testing is estimated to be 36,271hours (145,084 × 0.25 hour).

We estimate that records of testing, diversion, and treatment under § 118.10(a)(3)(v) to (a)(3)(viii) will be kept annually in the event a layer house tests environmentally negative for SE. We estimate that 5,965 layer and pullet houses will test negative and thus 5,965 recordkeepers will maintain one record of that testing that will take approximately 0.5 hour per record. Thus, the total annual burden for testing, diversion, and treatment records in the event of a negative test result is estimated to be 2,983 hours (5,965 × 0.5 hour).

Prevention plan review and modifications under § 118.10(a)(4) will need to be performed every time a house tests positive. As discussed, we estimate that 331 layer houses will test positive requiring plan review and modifications and that it will take 10 hours to complete this work. Thus, the total annual burden for prevention plan review and modifications in the event of a positive test result is estimated to be 3,310 hours (331 × 10 hours).

We estimate that chick and pullet procurement records under § 118.10(a)(2) will be kept roughly once annually per layer house basis. We estimate that 4,731 layer houses will maintain 1 record each and that it will take approximately 0.5 hour per recordkeeping. Thus, the total annual burden for chick and pullet procurement recordkeeping is estimated to be 2,366 hours (4,731 × 0.5 hour).

We estimate that rodent and other pest control records under § 118.10(a)(3)(ii)) and biosecurity records under § 118.10(a)(3)(i) will be kept weekly on a per layer house basis. We assume that 4,731 layer houses will maintain a weekly record under each provision. Thus, we estimate 9,462 recordkeepers will maintain 52 records each for a total of 492,024 records. We estimate a recordkeeping burden of 0.5 hours per record for a total of 246,012 burden hours (492,024 × 0.5 hour).

New prevention plan design required by § 118.10(a)(1) will only be undertaken by new farms and records will be kept on a per farm basis. We estimate that there are 150 new farm registrations annually and we assume that this reflects 150 new farms requiring prevention plan design. We estimate that it will take 20 hours to complete this work. Thus, the total annual burden for prevention plan design is estimated to be 3,000 hours (150 × 20 hours).

Cleaning and disinfection recordkeeping under § 118.10(a)(3)(iii) will need to be performed every time a house tests positive. As discussed, we estimate that 331 layer houses will test positive requiring 1 record each and that it will take approximately 0.5 hour per recordkeeping. Thus, the total annual burden for cleaning and disinfection recordkeeping in the event of a positive test result is estimated to be 166 hours (331 × 0.5 hour).

Reporting Burden

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Description and 21 CFR section	FDA form No.	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Registrations or Updates, § 118.11	Form FDA 3733 [2]	150	1	150	2.3	345
Cancellations, § 118.11	Form FDA 3733	15	1	15	1	15
Total						360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *http://www.access.fda.gov* per § 118.11(b)(1).

This estimate is based on FDA's experience implementing the Shell Eggs final rule and the average number of new Shell Egg Producer registrations and cancellations received in the past 3 years under § 118.11. Based on FDA experience with implementing the registration provisions of the Shell Eggs final rule, which had staggered compliance dates and gave producers with fewer than 50,000 but at least 3,000 laying hens until July 9, 2012, to register (74 FR 33030 at 33034), FDA expects that it will receive fewer registrations or updates each year over the next 3 years, reflecting compliance with the final rule's registration deadlines. FDA estimates that it will receive 200 registrations or updates in 2013, 150 registrations or updates in 2014, and 100 registrations or updates in 2015, for an average of 150 registrations or updates per year over the next 3 years. FDA received 12 cancellations in 2011 and 19 cancellations in 2012. Based on this experience, FDA estimates that it will receive approximately 15 cancellations per year over the next 3 years.

FDA estimated in the Shell Eggs final rule that listing the information required by the final rule and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 2.3 hours per average registration. As detailed in section V.F of the final rule (see 74 FR 33030 at 33080), FDA estimates that it will take the average farm 2.3 hours to register taking into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new Shell Egg Producer registrations or updates is estimated to be 345 hours (150 × 2.3 hours).

FDA estimates cancelling a registration will, on average, require a

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