

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2011-N-0231]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Experience Reporting for Licensed Biological Products; and General Records****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Adverse Experience Reporting for Licensed Biological Products; and General Records" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-7726, [ila.mizrachi@fda.hhs.gov](mailto:ila.mizrachi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On July 19, 2011, the Agency submitted a proposed collection of information entitled "Adverse Experience Reporting for Licensed Biological Products; and General Records" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0308. The approval expires on November 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: November 18, 2011.

**Leslie Kux,***Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-30326 Filed 11-23-11; 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**Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the draft guidance entitled "Tobacco Retailer Training Programs."

**DATES:** Submit written or electronic comments on the collection of information by January 24, 2012.

**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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-5156, [daniel.gittleston@fda.hhs.gov](mailto:daniel.gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of July 16, 2010 (75 FR 41498), FDA published a notice of availability of the draft guidance document providing a 60-day public comment period on the collection of information provisions. An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> (Docket No. FDA-2010-D-0350) and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>. FDA received seven comments in response to the notice of availability, with four comments pertaining to the information collection.

FDA is republishing notice of the proposed collection of information in order to comply with section 3506(c)(2)(A) of the PRA. We invite comments only on the proposed collection of information set forth in this document. FDA will respond to comments on the collection of information provisions received in response to this notice and to the July 16, 2010, notice in a 30-day notice announcing that a proposed collection of information has been submitted to OMB for review and clearance under the PRA.

With respect to the collection of information associated with the draft guidance, 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.

**Information Request Regarding Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs (OMB Control Number 0910-New)**

The Tobacco Control Act 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 promulgated under section 906(d) of the Federal Food,

Drug, and Cosmetic Act, as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by the FDA for such programs. The FDA intends to promulgate regulations establishing standards for approved retailer training programs. In the interim, the draft guidance is intended to assist tobacco retailers in implementing effective training programs for employees.

The draft 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; and (5) age verification methods. The draft 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 draft 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 draft guidance also recommends that retailers implement certain hiring and management practices as part of an effective retailer training program. The draft 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 of this document 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 Sytar 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 draft guidance, some retailers would update their training program to meet the elements in the draft 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 draft guidance (66 percent of 410,000 = 270,600).

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

TABLE 1—ESTIMATED ONE TIME REPORTING BURDEN<sup>1</sup>

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
<b>Total .....</b>					<b>6,765,000</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

Activity	Number of Record-keepers	Annual frequency per record-keeping	Total annual records	Hours per record	Total hours
Training program .....	270,600	4	1,082,400	.25	270,600
Written policy against sales to minors & employee acknowledgment .....	270,600	4	1,082,400	.10	108,240
Internal compliance check program .....	270,600	2	541,200	.5	270,600
<b>Total .....</b>					<b>649,440</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 18, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-30327 Filed 11-23-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0841]

#### Agency Emergency Processing Under the Office of Management and Budget Review; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Food Safety Modernization Act: Economic Hardship Fee Reduction Guidance

**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 (PRA). The proposed collection of information concerns a guidance document that outlines the criteria and the process through which firms may request a reduction of fees based on severe economic hardship of the FDA Food Safety Modernization Act (FSMA) reinspection and recall user fees that are mandated by the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

**DATES:** Fax written comments on the collection of information by December 15, 2011. FDA is requesting OMB approval of this emergency processing by January 6, 2012.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title "FDA Food Safety Modernization Act: Economic Hardship Fee Reduction Guidance." Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information

Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-3793.

**SUPPLEMENTARY INFORMATION:** FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). FDA requests permission to use the emergency clearance procedures to obtain OMB approval of the information collection related to the economic hardship fee reduction guidance. FDA expects to use a print-and-mail or an email form for fee reduction requests. If FDA were to use the normal clearance procedures, the approval of the information collection would not be finalized in time to issue invoices in January 2012. FDA seeks OMB approval of the information collection by January 6, 2012, so the Agency can issue such guidance no later than January 2012.

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.

#### FDA Food Safety Modernization Act: Economic Hardship Fee Reduction Guidance (OMB Control Number 0910-NEW)

On January 4, 2011, the President signed into law FSMA (Pub. L. 111-353). Section 743 of the FD&C Act (21 U.S.C. 379j-31) amended by FSMA, requires FDA to consider the burden of fee amounts on small businesses.

Section 743(b)(2)(B)(iii) of FD&C Act states, " \* \* \* the Secretary shall publish in the **Federal Register** a proposed set of guidelines in consideration of the burden of fee amounts on small business. Such consideration may include reduced fee amounts for small businesses. \* \* \*" Before publishing such guidelines, FDA believes it is important to gather additional information related

to small business burdens associated with fees to set forth criteria and a rational for such criteria for when a user fee reduction is appropriate. Therefore, FDA published a document in the **Federal Register** of August 1, 2011 (76 FR 45818) (FRN) to seek public comments and information to assist the Agency to develop such guidelines. FDA will review the comments (comment period closes on November 30, 2011) and then develop the proposed set of guidelines; these will likely be implemented in fiscal year (FY) 2013. However, FDA recognizes that, meanwhile, for some small businesses the reinspection or the recall user fees, which went into effect on October 1, 2011, could impose severe economic hardship and there may be unique circumstances in which some relief would be appropriate. During FY 2012, FDA will consider waiving some or all of an invoiced fee based on a severe economic hardship. FDA intends to protect businesses and preserve free competitive enterprise.

FDA is currently developing a guidance to outline the criteria and the process through which firms may request a reduction of fees based on economic hardship. FDA wants to consider the public comments from the small business FRN before finalizing such guidance. Also, in the recent "Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act" that published in the **Federal Register** of October 6, 2011 (76 FR 62073), FDA stated that it would "not intend to issue invoices for reinspection or recall order fees until this guidance document has been finalized." Therefore, FDA needs to publish such guidance soon after November 30, 2011, in order to: (1) Issue invoices and (2) provide important information for qualified firms to apply for fee reductions, which will help them to sustain their businesses. Given such a short timeframe, use of the normal clearance process to obtain OMB approval under the PRA for the information collection related to the economic hardship fee reduction guidance is likely to cause delay of publishing such guidance and subsequently cause delay of issuing invoices. The fees, required by FSMA, are to cover 100 percent of the costs of certain reinspection and recall order activities conducted by FDA.

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