both the general public and the professional communities. This submission is for generic approval and will provide for formative and qualitative evaluation activities to (1) assess audience knowledge, attitudes, behavior and other characteristics for the planning and development of messages, communication strategies and public information programs; and (2) test these messages, strategies and program components in developmental form to assess audience comprehension, reactions and perceptions. Information obtained from testing can then be used to improve materials and strategies while revisions are still affordable and possible. The annual burden associated with these activities is summarized below.

| Activity | Nunmber of respondents | Responses/ respondent | Hours per response | Total hours |
|---|---|---|---|---|
| Individual In-depth Interviews: | | | | |
| General Public | 400 | 1 | .75 | 300 |
| Service Providers | 200 | 1 | .75 | 150 |
| Focus Group Interviews: | | | | |
| General Public | 3,000 | 1 | 1.5 | 4,500 |
| Service Providers | 1,500 | 1 | 1.5 | 2,250 |
| Telephone Interviews: | | | | |
| General Public | 335 | 1 | .08 | 27 |
| Service Providers | 165 | 1 | .08 | 13 |
| Self-Administered Questionnaires: | | | | |
| General Public | 2,680 | 1 | .25 | 670 |
| Service Providers | 1,320 | 1 | .25 | 330 |
| Gatekeeper Reviews: | | | | |
| General Public | 1,200 | 1 | .50 | 600 |
| Service Providers | 900 | 1 | .50 | 450 |
| Total | 11,700 | | | 9,290 |

Written comments and recommendations concerning the proposed information collection should be sent by August 16, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: July 9, 2010.

**Elaine Parry,**

*Director, Office of Program Services.*

[FR Doc. 2010–17358 Filed 7–15–10; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–D–0350]**

### Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for tobacco retailers entitled "Tobacco Retailer Training Programs." The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) does not require retailers to implement retailer training programs. However, the Tobacco Control Act does provide for lower civil money penalties for violations of access, advertising, and promotion restrictions issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act (the act), 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, this draft guidance document is intended to assist tobacco retailers who wish to implement effective training programs for employees.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance and on the proposed collection of information by September 14, 2010.

**ADDRESSES:** Submit electronic comments on the draft guidance, including comments regarding the proposed collection of information to *http://www.regulations.gov*. Submit written comments on the draft guidance, including comments regarding the proposed 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.

Submit written requests for single copies of the draft guidance document entitled "Tobacco Retailer Training Programs" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

*With regard to the draft guidance*: Beth Buckler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 1–877–287–1373, *beth.buckler@fda.hhs.gov*.

*With regard to the proposed collection of information*: JonnaLynn Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50, Rockville, MD 20850, 301–796–3794.

**SUPPLEMENTARY INFORMATION:**

## I. Background

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

Among its many provisions, section 906(d) of the act, as amended by the Tobacco Control Act, states that "[t]he Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health."

In accordance with section 102 of the Tobacco Control Act, FDA re-issued its 1996 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco products. The regulation is deemed to be issued under Chapter 9 of the act, as amended by the Tobacco Control Act. The regulation contains: Provisions designed to limit young people's access to cigarettes and smokeless tobacco products, as well as restrictions on advertising and promotion of such products, to curb the appeal of these products to minors (75 FR 13225; March 19, 2010).

Section 103(q) of the Tobacco Control Act directs the agency to issue guidance regarding penalties retailers are subject to for violations of the restrictions issued under section 906(d) of the act, as amended by the Tobacco Control Act. FDA intends to issue a draft guidance document shortly that will describe the penalties that apply to retailers for violations of the requirements of the act, as amended by the Tobacco Control Act, and implementing regulations and establish the policies and procedures for assessing civil money penalties.

Section 103(q)(2) of the Tobacco Control Act includes two schedules for assessing civil money penalties against retailers for violations of restrictions issued under section 906(d) of the act, as amended by the Tobacco Control Act, pertaining to the sale and distribution of a tobacco product, including access, promotion, and advertising restrictions. Under each schedule, violators are subject to increasing penalties for multiple violations within prescribed time periods. For the first three violations in a 24-month period, retailers with an approved training program are subject to lower penalties than retailers without such programs. Section 103(q)(2)(B) defines "approved training program" as a training program that complies with standards developed by FDA for such programs. The act further provides that the amount of the civil money penalty ultimately assessed shall take into account, among other things, the degree of culpability of the violator. (21 U.S.C. 333(f)(5)(B), as amended by the Tobacco Control Act).

FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, however, FDA is issuing this draft guidance to provide recommendations on elements the agency believes should be included in an effective retailer training program. Until FDA issues these regulations, the agency intends to use the lower maximum civil money penalties schedule for all retailers who violate the regulations restricting the sale and distribution of cigarettes and smokeless tobacco products (75 FR 13225; March 19, 2010), whether or not they have implemented a training program. However, FDA may consider further reducing the civil money penalty for retailers who have implemented a training program.

In the **Federal Register** of December 9, 2009 (74 FR 65129), FDA established a public docket to obtain information on suggested elements for tobacco retailer training programs. The draft guidance incorporates information FDA received in response to the request for comments.

## II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on "Tobacco Retailer Training Programs." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Paperwork Reduction Act of 1995

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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this 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.

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 issued under section 906(d) of the 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 issue 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.

**Draft Guidance for Tobacco Retailer Training Programs—(OMB Control Number 0910–NEW)**

This 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 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 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[1]

| Activity | No. 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.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| Activity | No. of Recordkeepers | Annual Frequency per Recordkeeping | 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 |
| Total | | | | | 649,440 |

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

## V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: July 12, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–17312 Filed 7–15–10; 8:45 am]

**BILLING CODE 4160–01–S**