4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0350]

Guidance for Tobacco Retailers on Tobacco Retailer Training Programs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a 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 sale and distribution, including youth access, advertising, and promotion restrictions issued under the Federal Food, Drug, and Cosmetic Act (the FD&C 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 guidance document is intended to assist tobacco retailers who wish to implement training programs for employees.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance 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 guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for tobacco retailers entitled "Tobacco Retailer Training Programs." This guidance document is intended to assist tobacco retailers who wish to implement training programs for employees.

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111-31; 123 Stat. 1776) 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.

Among its many provisions, section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), 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 (21 U.S.C. 387a-1), FDA re-issued its 1996 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco products (75 FR 13225, March 19, 2010). The regulation is deemed to be issued under chapter 9 of the FD&C Act, as amended by the Tobacco Control Act (section 102(a)(1)(A) of 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 (part 1140 (21 CFR part 1140)).

Section 103(q)(2) of the Tobacco Control Act (21 U.S.C. 333 note) includes two schedules for assessing the maximum civil money penalties against retailers for violations of restrictions issued under section 906(d) of the FD&C Act, as amended by the Tobacco Control Act, pertaining to the sale and distribution, including youth access, and advertising and promotion of tobacco products. 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.

FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, however, FDA is issuing this guidance to provide recommendations on elements the Agency believes should be included in a 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 (part 1140), 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 July 16, 2010 (75 FR 41498), FDA announced the availability of a draft guidance entitled "Tobacco Retailer Training Programs." The Agency considered received comments as it finalized this guidance. In addition, editorial changes were made to improve clarity.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 statutes and regulations.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of 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, and will be posted to the docket at http://www.regulations.gov.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44

U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0745.

V. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.regulations.gov or http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.

Dated: August 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-21547 Filed 09/04/2013 at 8:45 am; Publication Date: 09/05/2013]