

(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](mailto: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 (Pub. L. 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.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

##### **Allergenic Products Advisory Committee; Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Allergenic Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 5, 2013, from 9 a.m. to approximately 3:30 p.m. and on November 6, 2013, from 8:30 a.m. to approximately 2:45 p.m.

*Location:* FDA, 5630 Fishers Lane, Conference Room 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be webcast. The webcast will be available at the following links:

November 5, 2013: <http://fda.yorkcast.com/webcast/Viewer/?peid=3074a2c9f7ac478db3303477ac1c146b1d>.

November 6, 2013: <http://fda.yorkcast.com/webcast/Viewer/?peid=2f114f7579ef42e8b4ca4523b0b26eb51d>.

*Contact Person:* Donald Jehn or Joanne Lipkind, Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, MD 20852, 301-827-0314, [Donald.Jehn@fda.hhs.gov](mailto:Donald.Jehn@fda.hhs.gov) or [Joanne.Lipkind@fda.hhs.gov](mailto:Joanne.Lipkind@fda.hhs.gov), FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On November 5, 2013, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of Oralair, a Sweet Vernal Grass, Perennial Ryegrass, Timothy Grass, Orchard Grass, and Kentucky Bluegrass Mixed Pollens Allergen Extract tablet for sublingual use, manufactured by Stallergenes. On November 6, 2013, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of Grastek, a Timothy Grass Pollen Allergen Extract tablet for sublingual use, manufactured by Merck.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 29, 2013. Oral presentations from the public will be scheduled between approximately 12 noon and 12:30 p.m. on November 5, 2013, and between approximately 11:10 a.m. and 11:40 a.m. on November 6, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 21, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 22, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald Jehn or Joanne Lipkind at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 29, 2013

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Health Resources and Services Administration**
**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received within 30 days of this notice.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Develop and Implement UCARE4LIFE Message Library OMB No. 0915-xxxx-New.

**Abstract:** This project will develop and implement the UCARE4LIFE message library aimed at increasing HIV primary care retention rates for racial and ethnic minority youth aged 15 to 24, living with HIV/AIDS. The primary aims are (1) to develop, test, and