Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *CRDAC@fda.hhs.gov,* or 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:* The committee will discuss new drug application (NDA) 206316, edoxaban tablets, submitted by Daiichi Sankyo, Inc., for the prevention of stroke and systemic embolism (blood clots other than in the head) in patients with nonvalvular atrial fibrillation (A Fib; abnormally rapid and chaotic contractions of the atria, the upper chambers of the heart).

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 16, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 7, 2014. 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 8, 2014.

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 Kristina Toliver 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: September 11, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–22071 Filed 9–16–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0001]**

### Electronic Cigarettes and the Public Health; Public Workshop

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA), Center for Tobacco Products, is announcing a public workshop to obtain information on electronic cigarettes and the public health. The workshop will include presentations and panel discussions about the current state of the science, and will focus on product science, packaging, constituent labeling, and environmental impacts. FDA intends to follow this workshop with two additional electronic cigarette workshops, with one on individual health effects and one on population health effects.

*Dates and Times:* The public workshop will be held on December 10, 2014, from 8 a.m. to 5 p.m. and on December 11, 2014, from 8:30 a.m. to 3:30 p.m. Individuals who wish to attend the public workshop must register by November 25, 2014.

*Location:* The public workshop will be held at the FDA White Oak Conference Center, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking, transportation, security, and information regarding special accommodations due to a disability, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

*Contact Person:* Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *workshop.CTPOS@fda.hhs.gov.*

*Registration to Attend the Workshop:* If you wish to attend the workshop in person or by Webcast, you must register by submitting either an electronic or written request no later than November 25, 2014. Please submit electronic requests at *https://www.surveymonkey.com/s/CTP-December-Workshop.* Persons without Internet access may send written requests for registration to Caryn Cohen (see *Contact Person*). Requests for registration must include the prospective attendee's name, title, affiliation, address, email address if available, and telephone number. Registration is free and you may register to either attend in-person or view the live Webcast. Both seating and viewership are limited, so early registration is recommended. FDA may limit the number of registrants from a single organization, as well as the total number of participants, if registration reaches full capacity. For those registrants with Internet access, confirmation of registration will be emailed to you no later than November 26, 2014. Onsite registration may be allowed if space is available. If registration reaches maximum capacity,

FDA will post a notice closing registration at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm*. If you need special accommodations due to a disability, please contact Caryn Cohen (see *Contact Person*) no later than December 3, 2014.

*Presenters and Panelists:* FDA is interested in gathering scientific information from individuals with a broad range of perspectives on technical topics to be discussed at the workshop. To be considered to serve as a presenter, please provide the following:

- A brief abstract for each presentation. The abstract should identify the specific topic(s) to be addressed and the amount of time requested.
- A one-page biosketch that describes and supports the speaker's scientific expertise on the specific topic(s) being presented, nature of the individual's experience and research in the scientific field, positions held, and any program development activities.

Panelists will sit on a panel to discuss their scientific knowledge on the questions and presentations in each session. To be considered to serve as a panelist, please provide the following:

- A one-page biosketch that describes and supports the speaker's scientific expertise on the specific topic(s) being presented, nature of the individual's experience and research in the scientific field, positions held, and any program development activities.

If you are interested in serving as a presenter or panelist, please submit the above information, along with the topic on which you would like to speak, to *workshop.CTPOS@fda.hhs.gov* by November 4, 2014.

*Oral Presentations by Members of the Public:* This workshop includes a public comment session. Persons wishing to present during the public comment session must make this request at the time of registration and should identify the topic they wish to address from among those topics under consideration, which are identified in section II. FDA will do its best to accommodate requests to present. FDA urges individuals and organizations with common interests to consolidate or coordinate their comments, and request a single time for a joint presentation. For those requesters with Internet access, Caryn Cohen (see *Contact Person*) will email you regarding your request to speak by November 26, 2014.

*Transcripts:* A transcript of the proceedings will be available after the workshop at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm* as soon as the official transcript is finalized. It will also be posted to the docket at *http://www.regulations.gov* once the docket is opened.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing a public workshop to gather scientific information and stimulate discussion among scientists about electronic cigarettes (e-cigarettes). The focus of this workshop will be product science (specifically device designs and characteristics, and e-liquid and aerosol constituents), product packaging, constituent labeling, and environmental impact. FDA intends to follow this workshop with two additional workshops that will address other scientific topics related to e-cigarettes, including: (1) The impact of e-cigarettes on individual health, including clinical pharmacology, topography, abuse liability, dependence, and health effects and (2) the impact of e-cigarettes on the population, including discussions of product appeal (e.g., impact of advertising, marketing, flavorings, consumer perceptions) and product safety labeling.

On April 25, 2014, FDA published a proposed rule to extend its tobacco product authorities to additional products that meet the statutory definition of ''tobacco product'' (Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; 79 FR 23141, April 25, 2014, Docket No. FDA–2014–N–0189) (proposed deeming rule). If the proposed deeming rule is finalized as proposed, e-cigarettes that are tobacco products would be subject to FDA regulation under the FD&C Act. As stated in the proposed deeming rule, FDA ''is aware of the recent significant increase in the prevalence in e-cigarette use'' (79 FR 23141 at 23152), and there is much to be learned about these relatively new entrants to the market.

These workshops are intended to better inform FDA about these products. Should the Agency move forward as proposed to regulate e-cigarettes, additional information about the products would assist the Agency in carrying out its responsibilities under the law. This would be true regardless of the details of any such final rule. Accordingly, FDA is working to obtain such information now rather than waiting for the conclusion of the deeming rulemaking.

Participants should note that this workshop is not intended to inform the Agency's deeming rulemaking. All comments regarding the proposed deeming rule were to be submitted to the Agency by August 8, 2014 (Docket No. FDA–2014–N–0189). As such, the scope of this workshop is limited to the topics presented in Section II.

At the start of this first workshop in this series, FDA will announce via a **Federal Register** notice the establishment of a docket for submission of written comments. Regardless of attendance at the public workshops, interested persons will be invited to submit comments to the docket. The forthcoming **Federal Register** notice will provide information on how to submit comments. Please note that this docket will only pertain to this workshop. Comments submitted to the docket will not be added to other dockets, such as the docket for the proposed rule deeming additional tobacco products subject to the FD&C Act.

## II. Topics for Discussion

The public workshop will include presentations and panel discussion regarding e-cigarettes and the public health, specifically relating to the products themselves. Topics to be addressed include, for example: (1) Product science (including design, chemistry, and toxicology); packaging, labeling, and environmental impact assessments; (2) potential risks and benefits of product characteristics; (3) strategies to mitigate risk to users; (4) methods for evaluating product performance, constituents, stability, etc.; and (5) potential risks to the environment. Additional information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm*.

Dated: September 11, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–22122 Filed 9–16–14; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as