4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1936]

# 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. This will be the second in a series of three workshops. The workshop will include presentations and panel discussions about the current state of the science and will focus on individual health impacts. FDA intends to follow this workshop with an electronic cigarette workshop on population health effects.

Dates and Times: The public workshop will be held on March 9, 2015, from 8 a.m. to 5 p.m. and on March 10, 2015, from 8 a.m. to 5 p.m. Individuals who wish to attend the public workshop must register by February 20, 2015.

Location: The public workshop will be held at the Marriott Inn and Conference Center, University of Maryland University College, Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301-985-7300.

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 an electronic or written request no later than February 20, 2015. Please submit electronic requests at https://www.surveymonkey.com/s/CTP-March-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 attend in person or view the live Webcast. Seating and viewership are limited, so early registration is recommended. FDA may limit the number of registrants from a single organization and the total number of participants if registration reaches full capacity. For registrants with Internet access, confirmation of registration will be emailed to you no later than February 23, 2015. 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 March 2, 2015.

Presenters and Panelists: FDA is interested in gathering scientific information from individuals with a broad range of backgrounds on the scientific topics to be discussed at the workshop. To be considered 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 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 requested information, along with the topic on which you would like to speak, to workshop.CTPOS@fda.hhs.gov by January 22, 2015.

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 that 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 during the public comment period by February 23, 2015.

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.

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 the impact of e-cigarettes on individual health, including user exposure, topography, abuse liability, dependence, and short and long-term health effects. A workshop focusing on product science, product packaging, constituent labeling, and environmental impact was held in December 2014. FDA intends to follow this workshop with an additional workshop that will address 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 (FD&C 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 the first workshop in this series, FDA announced via a Federal Register notice the opening of a docket for submission of written comments regarding all three workshops (see Establishment of a Public Docket; Electronic Cigarettes and the Public Health Workshop, Docket No. FDA-2014-N-1936, http://www.gpo.gov/fdsys/pkg/FR-2014-12-02/pdf/2014-28261.pdf). Regardless of attendance at the public workshops, interested persons are invited to submit comments to the docket. 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 impact of e-cigarettes on individual health. Topics to be addressed include, for example: (1) Topography; (2) exposures and toxicological considerations; (3) pharmacokinetics and pharmacodynamics of nicotine exposure in users; (4) abuse liability and dependence; (5) short and long-term health effects in users; (6) considerations for high risk or vulnerable populations; and (7) human factors. 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: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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