4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0173]

Waterpipes and Waterpipe Tobacco; Public Workshop; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing a public workshop to gather scientific information on waterpipes and waterpipe tobacco and to identify areas of research that may inform CTP's regulation of these tobacco products. The workshop will include presentations and panel discussions about the current state of the science, and will focus on product use and design, smoke constituents, environmental impacts, and the impact of marketing these products on population health, including on both users and nonusers. FDA is also opening a public docket to receive data, information, and comments on this topic.

DATES: The public workshop will be held on March 17, 2016, from 8:30 a.m. to 5 p.m. and on March 18, 2016, from 8:30 a.m. to 4 p.m. Individuals who wish to attend the public workshop must register by February 25, 2016. Submit written or electronic comments to Docket No. FDA-2016-N-0173 by April 29, 2016.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993. Entrance for the public workshop 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.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0173 for "Waterpipes and Waterpipe Tobacco; Public Workshop; Establishment of a Public Docket." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: 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, workshop.CTPOS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop to gather scientific information and stimulate discussion among scientists about waterpipes and waterpipe tobacco. The workshop will focus on waterpipe tobacco product toxic emissions and exposure to harmful and potentially harmful constituents including: Second hand exposure, design and environmental concerns, prevalence, perception, use pattern, addiction, individual and population health. 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. 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.

II. 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 February 25, 2016. Please submit electronic requests at https://www.surveymonkey.com/r/Waterpipes2016. Persons without Internet access may send written requests for registration to Caryn Cohen (see FOR FURTHER INFORMATION CONTACT). 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 March 1, 2016. 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 FOR FURTHER INFORMATION CONTACT) no later than March 10, 2016.

III. 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. 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 FOR FURTHER INFORMATION CONTACT) will email you regarding your request to speak by March 1, 2016.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at http://www.fda.gov. It will also be available after the workshop at http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm as soon as the official transcript is finalized.

Dated: February 18, 2016.

Leslie Kux,

Associate Commissioner for Policy

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