

service animals. Once cleared for entry to the complex participants will be directed to visitor parking by a security officer.

To ensure expedited entry into the building it is recommended that participants have their government ID and a copy of their written meeting registration confirmation readily available and that they do not bring large/bulky items into the building. Participants are reminded that photography on the CMS complex is prohibited. CMS has also been declared a tobacco free campus and violators are subject to legal action. In planning arrival time, we recommend allowing additional time to clear security. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The invited guests may not enter the building earlier than 45 minutes before the convening of the meeting each day.

Guest access to the complex is limited to the meeting area, the main entrance lobby, and the cafeteria. If a visitor is found outside of those areas without proper escort they may be escorted off of the premises. Also be mindful that there will be an opportunity for everyone to speak and we request that everyone waits for the appropriate time to present their product or opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex. No visitor is allowed to attach USB cables, thumb drives or any other equipment to any CMS information technology (IT) system or hardware for any purpose at any time. Additionally, CMS staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Special arrangements and approvals are required at least 2 weeks prior to each public meeting to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures. Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

Foreign National Visitors are defined as Non-US Citizens, and non-lawful permanent residents, non-resident aliens or non-green-card holders.

Attendees that are foreign nationals must identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Building to Visit/Destination.
- Visit start date, start time, end date, end time.
- Visitor full name.
- Gender.
- Visitor Title.
- Visitor Organization/Employer.
- Citizenship.
- Birth Place (City, Country).
- Date of Birth.
- ID Type (Passport or State Department ID).
- Passport issued by Country.
- ID (passport) Number.
- ID (passport) issue date.
- ID (passport) expiration date.
- Visa Type.
- Visa Number.
- Purpose of Visit.

Dated: February 2, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4852]

Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period provided in the notice entitled “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability” that appeared in the **Federal Register** of January 26, 2016. That notice announced the availability of a draft guidance for industry and FDA staff and requested comments by March 28, 2016.

FDA is extending the draft guidance’s comment period by 30 days in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for the draft guidance “Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices” published on January 26, 2016 (81 FR 4303), by an additional 30 days. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 28, 2016.

ADDRESSES: 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–2015–D–4852 for “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices.” 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.

An electronic copy of the guidance document is available for download from the Internet. See the

SUPPLEMENTARY INFORMATION section for

information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Heather Agler, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5570, Silver Spring, MD 20993–0002, 301–796–6340; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 26, 2016 (81 FR 4303), FDA published a notice announcing the availability of a draft guidance entitled “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” with a 60-day comment period to request comments. FDA is extending the comment period for the draft guidance for 30 days, until April 28, 2016. The Agency believes that a 30-day extension will allow adequate time for interested persons to submit comments.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy

of “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500015 to identify the guidance you are requesting.

Dated: February 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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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