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 Submit written requests for a single hard copy of the draft guidance document entitled ''Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices'' to the Office of the Center Director,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 Premarket 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.

[FR Doc. 2016–03696 Filed 2–22–16; 8:45 am]

BILLING CODE 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.

[FR Doc. 2016–03712 Filed 2–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1503–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—October Through December 2015

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists of the OMHA Case Processing Manual (OCPM) manual instructions that were published from October through December, 2015. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT: Amanda Axeen, by telephone at (571) 777–2705, or by email at *amanda.axeen@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary of the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim, organization and coverage determination, and entitlement appeals under sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage Organizations (MAOs) and Medicaid State Agencies, have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D Plan Sponsors (PDPSs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related monthly adjustment amounts (IRMAA) made by the Social Security Administration (SSA).

The Medicare claim, organization and coverage determination appeals processes consist of four levels of administrative review, and a fifth level of review with the Federal district courts after administrative remedies under HHS regulations have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors for claim appeals, by MAOs and an independent review entity for Part C organization determination appeals, or by PDPSs and an independent review entity for Part D coverage determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals Council. In addition, OMHA and the DAB administer the second and third levels of appeal, respectively, for Medicare eligibility, entitlement, Part B late enrollment penalty, and IRMAA reconsiderations made by SSA; a fourth level of review with the Federal district courts is available after administrative remedies within SSA and HHS have been exhausted.

Sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Act are implemented through the regulations at 42 CFR part 405 subparts I and J; part 417, subpart Q; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. As noted above, OMHA administers the nationwide Administrative Law Judge hearing program in accordance with these statutes and applicable regulations. As part of that effort, OMHA is establishing a manual, the OMHA Case Processing Manual (OCPM). Through the OCPM, the OMHA Chief Administrative Law Judge establishes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations and OMHA directives. The OCPM provides direction for processing appeals at the OMHA level of adjudication for Medicare Part A and B claims; Part C organization determinations; Part D coverage determinations; and SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides the specific updates to the OCPM that have occurred in the 3-month period. A hyperlink to the available chapters on the OMHA Web site is provided below. The OMHA Web site contains the most current, up-to-date chapters and revisions to chapters, and will be available earlier than we publish our quarterly notice. We believe the OMHA Web site list provides more timely access to the current OCPM chapters for those involved in the Medicare claim, organization and coverage determination and entitlement appeals processes. We also believe the Web site offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive immediate notification of any updates to the OMHA Web site. This listserv avoids the need to check the OMHA Web site, as update notifications are sent to subscribers as they occur. If accessing the OMHA Web site proves to be difficult, the contact person listed above can provide the information.

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the