

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, Switzer Building, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018-02869 Filed 2-12-18; 8:45 am]

BILLING CODE 4184-23-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6888]

Neurological Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the *Federal Register* of December 28, 2017. The amendment is being made to reflect a change in the *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993-0002, Aden.Asefa@fda.hhs.gov, 301-796-0400, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code NE. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of December 28, 2017, 82 FR 61574, FDA announced that a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee would be held on March 1, 2018, from 8 a.m. to 6 p.m. On page 61574, in the 3rd column, the *Procedure* portion of the document is changed to read as follows:

Procedure: FDA will work with affected industry organizations that have an interest in intracranial aneurysm treatment devices and who wish to make a presentation separate from the general Open Public Hearing; time slots on March 1, 2018, between approximately 9:40 a.m. and 11 a.m. Representatives from industry organizations interested in making formal presentations to the committee should notify the contact person on or before February 16, 2018.

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 February 16, 2018. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. 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 February 9, 2018. 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 February 12, 2018.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-02766 Filed 2-12-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0235]

Orthopaedic Sensing, Measuring, and Advanced Reporting Technology Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Orthopaedic Sensing, Measuring, and Advanced Reporting Technology (SMART) Devices." The purpose of the public workshop is to discuss the development of Orthopaedic SMART Devices. The workshop is intended to enhance engagement with stakeholders to facilitate device development and to discuss scientific and regulatory challenges associated with Orthopaedic SMART Devices. Public input and feedback gained through this workshop may aid in the efficient development of innovative, safe, and effective Orthopaedic SMART Devices for better patient care.

DATES: The public workshop will be held on April 30, 2018, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by May 29, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (The Great Room), 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 and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 29, 2018. The <https://>

www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of May 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2018-N-0235 for "Orthopaedic Sensing, Measuring, and Advanced Reporting Technology Devices; Public Workshop; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the

Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew Baumann, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 62, Rm. 2110, Silver Spring, MD 20993, 301-796-2508, andrew.baumann@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is sponsoring a public workshop to discuss the engineering, clinical, regulatory, cybersecurity, and real world evidence aspects of Orthopaedic SMART Devices. The technologies of interest incorporate sensor equipped implants and instruments that generate information related to orthopaedic

device performance and patient health. FDA understands that these technologies will play a role in the future of orthopaedics by providing objective data to the appropriate stakeholder that may optimize patient care. A public discussion of these topics will help the orthopaedic medical device community better understand the development of and considerations for these technologies. The workshop may help FDA and stakeholders prepare for the submittal and review of related applications.

II. Topics for Discussion at the Public Workshop

The public workshop will consist of presentations and panel discussions. Presentations will frame the topic and provide information on specific aspects of orthopaedic SMART device technology. Following the presentations, moderated discussions will ask speakers and additional panelists to provide their individual perspectives. Four rounds of presentations and panel discussions will cover the following topics:

- **Engineering/Technology (morning)**
This session will introduce orthopaedic sensor technologies and cover the current state of research and industry adoption. Future applications of these technologies will be explored.
- **Clinical/Patient perspective (morning)**
This session will cover the importance and potential utility of these technologies for clinicians and patients. Considerations for adopting these new technologies into existing health care paradigms will be discussed.
- **Cybersecurity (afternoon)**
This session will cover current cybersecurity issues and considerations. An overview of FDA's cybersecurity considerations and guidance documents will be presented.
- **Regulatory Considerations (afternoon)**

This session will discuss FDA's current and evolving thinking on Digital Health, clinical study considerations, including the role of real-world evidence, relevant guidance documents, and evidence generation related to Orthopaedic SMART Devices.

A detailed agenda will be posted on the following website in advance of the workshop: <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> and select this event from the list of items provided.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical

Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 20, 2018, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993-0002, 301-796-5661, email: Susan.Monahan@fda.hhs.gov, no later than April 16, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration web page after April 20, 2018. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available approximately 45 days after the public workshop on the internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

Dated: February 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-02923 Filed 2-12-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0180]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications.”

DATES: Submit either electronic or written comments on the collection of information by April 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 16, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://](https://www.regulations.gov)

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 <https://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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2018-N-0180 for “Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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