

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Adoption Call to Action: Baseline Survey	53	1	.33	18	6
Adoption Call to Action: Progress Update	53	2	.25	27	9

Estimated Total Annual Burden Hours: 15.

Comments: 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.

Authority: Section 203 of Section II: Adoption Opportunities of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5113).

Molly B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020-03579 Filed 2-21-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0008]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on April 23, 2020, from 8 a.m. to 6 p.m.

and on April 24, 2020, from 8 a.m. to 1 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993-0002, Patricio.Garcia@fda.hhs.gov, 301-796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On April 23, 2020, during session I, the committee will discuss and make recommendations regarding the classification of facet screws systems, which are currently unclassified pre-amendment devices to class II (general and special controls). During session II, the committee will

discuss and make recommendations regarding the reclassification of noninvasive bone growth stimulators, which are currently post-amendment devices from class III (general controls and premarket approval) to class II (general and special controls).

On April 24, 2020, the committee will discuss and make recommendations regarding the classification of three devices, which are currently unclassified pre-amendment devices to class II (general and special controls). The committee, during session I, will discuss semiconstrained toe (metatarsophalangeal) joint prostheses; during session II, will discuss intracompartmental pressure monitors; and during session III, will discuss intra-abdominal pressure monitoring devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: 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 April 1, 2020. Oral presentations from the public will be scheduled on April 23, 2020, between approximately 8:15 a.m. and 8:45 a.m. and between approximately 1 p.m. and 1:30 p.m.; on April 24, 2020, between approximately 8:15 a.m. and 9:15 a.m. Those individuals interested in making formal oral presentations should notify the contact person and indicate during which session they would like to present (see **FOR FURTHER INFORMATION CONTACT**). The notification should include 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 March 24, 2020. 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 sessions. The contact person will notify interested persons regarding their request to speak by March 25, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at artair.mallett@fda.hhs.gov or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 19, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-03565 Filed 2-21-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1006]

Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final

guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7)." FDA has identified certain submission types that warrant an exemption (Type III drug master files (DMFs)) or a long-term waiver (certain positron emission tomography (PET) drug products and certain Type II DMFs supporting PET drugs or noncommercial submissions or applications) from the requirement to submit to the Agency in electronic common technical document (eCTD) format. In addition, this guidance outlines certain circumstances where FDA may determine that a short-term waiver from eCTD submission requirements could be granted. This guidance finalizes the revised draft guidance of the same title issued in July 2019 and replaces the final guidance issued in January 2019 (Revision 6).

DATES: The announcement of the guidance is published in the **Federal Register** on February 24, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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-2014-N-1006 for "Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7)." Received comments 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.govinfo.gov/content/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