II. Electronic Access

Persons interested in obtaining a copy of the 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 *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17038 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information have been approved by OMB as follows:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
803	Medical device reporting	0910–0437
807, subparts A through D	Registration and listing	0910–0625
807, subpart E	Premarket notification	0910–0120
812	Investigational device exemption	0910–0078
814, subparts A through E	Premarket approval applications	0910–0231
814, subpart H	Humanitarian use devices	0910–0332
820	Current good manufacturing practice and the quality system regulation.	0910–0073
312	Investigational New Drug Regulations	0910–0014
314	Applications for FDA Approval to Market a New Drug	0910–0001
314	Abbreviated New Drug Applications and 505(b)(2) Applications	0910–0786
601; Form FDA 356h	Biologics License; Application to Market a New Drug or Abbreviated New Drug or Biologic for Human Use—Form FDA 356h.	0910–0338
''User Fees for 513(g) Requests for Information'' and ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) requests	0910–0705
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo requests	0910–0844

Dated: July 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16394 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

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 take place virtually on September 8, 2020, from 8 a.m. to 6 p.m. Eastern Time and on September 9, 2020, from 8 a.m. to 1 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform held via webcast only. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* The meeting will be webcast both days and will be available at the following link:

Webcast link for Day 1: http://fda.yorkcast.com/webcast/Play/8ef8ac6b36f244beaced2a3031eebc621d.

Webcast link for Day 2: http://fda.yorkcast.com/webcast/Play/0e1b175674de4b1e8a4675cf5096aa601d.

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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 8, 2020, during session 1, 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 non-invasive 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 September 9, 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 semi-constrained 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 on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/orthopaedic-and-rehabilitation-devices-panel.*

Select the link for the 2020 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

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 August 28, 2020. Oral presentations from the public will be scheduled on September 8, 2020 between approximately 8:15 a.m. and 8:45 a.m. and between approximately 1 p.m. and 1:30 p.m.; on September 9, 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 August 20, 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 August 21, 2020.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 Mallet 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: July 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16436 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1294]

Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' This guidance describes FDA's current recommendations about endotoxin limits in certain investigational oncology drugs and biological products. This guidance looks at a risk-based approach of weighing the potential risks of not evaluating endotoxin levels in all components of a multidrug regimen against the potential benefits to patients with serious and life-threatening diseases.

DATES: Submit either electronic or written comments on the draft guidance by September 28, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–