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–

2020–D–1294 for ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Keegan, Center for Drug Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 22, Rm. 2322, Silver Spring, MD 20993, 301–796–1387; 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

FDA is announcing the availability of a draft guidance for industry entitled ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' When finalized, this guidance will describe FDA's current recommendations about endotoxin limits in investigational oncology drugs and biological products. It 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. It is limited to anticancer drugs administered parenterally (except for intraocular administration) to treat serious and life-threatening cancers based on histology or stage of disease.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: July 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16340 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information on Innovative Programs To Reconnect Youth to Education and Employment and Promote Self-Sufficiency

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: HHS issues this Request for Information (RFI) in order to seek information about programs that provide services to help young people, ages 16 to 24, advance on education and employment pathways. This project is focused on the population of young people who are out of work and/or out of school, particularly those from lower income families and communities, sometimes called disconnected or opportunity youth. The information gathered will result in a public compendium that profiles selected programs operating in this area, particularly innovative programs.

DATES: Submit written comments at the address provided below no later than September 28, 2020.

ADDRESSES: Written comments should be submitted to *ReconnectingYouthRFI@hhs.gov.* HHS encourages the early submission of comments.

FOR FURTHER INFORMATION CONTACT: Lisa Trivits on the Reconnecting Youth team at *ReconnectingYouthRFI@hhs.gov* or 202–205–9256.

SUPPLEMENTARY INFORMATION: *Invitation to Comment:* HHS invites comments