Burden Information Collection Reports, in all correspondence.

Jeffrey A. Koses,

Director, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2017–17831 Filed 8–22–17; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2017–0072, NIOSH–300]

Draft—National Occupational Research Agenda for Manufacturing

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comments.

SUMMARY: As steward of the National Occupational Research Agenda (NORA), the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of the draft National Occupational Research Agenda for Manufacturing for public comment. Written by the NORA Manufacturing Sector Council, the Agenda identifies the most important occupational safety and health research needs for the next decade, 2016–2026. A copy of the draft Agenda is available at *http://www.regulations.gov* (search Docket Number CDC–2017–0072).

DATES: Electronic or written comments must be received by October 23, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0072 and docket number NIOSH–300, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All submissions received must include the agency name and Docket Number [CDC–2017–0072; NIOSH–300]. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Emily Novicki (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE., Atlanta, GA 30329.

SUPPLEMENTARY INFORMATION: The National Occupational Research Agenda (NORA) is a partnership program created to stimulate innovative research and improved workplace practices. The national agenda is developed and implemented through the NORA sector and cross-sector councils. Each council develops and maintains an agenda for its sector or cross-sector.

The National Occupational Research Agenda for Manufacturing is intended to identify the research, information, and actions most urgently needed to prevent occupational injuries and illnesses in the manufacturing sector. The National Occupational Research Agenda for Manufacturing provides a vehicle for industry stakeholders to describe the most relevant issues, gaps, and safety and health needs for the sector. Each NORA research agenda is meant to guide or promote high priority research efforts on a national level, conducted by various entities, including: Government, higher education, and the private sector. The first National Occupational Research Agenda for Manufacturing was published in 2010 for the second decade of NORA (2006–2016). This draft is an updated agenda for the third decade of NORA (2016–2026). The revised agenda was developed considering new information about injuries and illnesses, the state of the science, and the probability that new information and approaches will make a difference.

As the steward of the NORA process, NIOSH invites comments on the draft National Occupational Research Agenda for Manufacturing. A copy of the draft Agenda is available at *http://www.regulations.gov* (see Docket Number CDC–2017–0072, NIOSH–300).

Dated: August 17, 2017.

Frank Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2017–17786 Filed 8–22–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4835]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Peripheral and Central Nervous System Drugs 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. FDA is establishing a docket for public comment on this document.

DATES: The public meeting will be held on September 28, 2017, from 9 a.m. to 4:30 p.m.

ADDRESSES: Tommy Douglas Conference Center, The Ballroom, 10000 New Hampshire Ave., Silver Spring, MD 20903. Answers to commonly asked questions about FDA Advisory Committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* Information about the Tommy Douglas Conference Center may be accessed at: *http://www.tommydouglascenter.com/.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–4835. The docket will close on September 27, 2017. Submit either electronic or written comments on this public meeting by September 27, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 27, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 27, 2017. 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.

Comments received on or before September 14, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

You may submit comments 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–2017–N–4835 for ''Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PCNS@fda.hhs.gov*; 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 Web site 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: The committee will discuss new drug application (NDA) 200896, ataluren for oral suspension, sponsored by PTC Therapeutics, Inc., for the treatment of patients with dystrophinopathy due to a nonsense mutation in the dystrophin gene.

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 Web site 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 Web site after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/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. All electronic and written submissions submitted to the docket (see **ADDRESSES**) on or before September 14, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. 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 September 6, 2017. 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 September 7, 2017.

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 special accommodations due to a disability, please contact Moon

Hee V. Choi at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site 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: August 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17856 Filed 8–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2464]

Advancing the Development of Pediatric Therapeutics: Application of ''Big Data'' to Pediatric Safety Studies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Office of Pediatric Therapeutics, Food and Drug Administration (FDA), is announcing a public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT): Application of ''Big Data'' to Pediatric Safety Studies.'' The purpose of this 2-day workshop is to understand how to access and analyze ''Big Data'' associated with safety information in the health care setting, and the utility and challenges associated with the use of ''Big Data'' to study the safety of therapeutics in children.

DATES: The public workshop will be held on September 18 and 19, 2017, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the DoubleTree by Hilton Hotel, 8727 Colesville Rd. (Route 29), Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Renan A. Bonnel, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8654, Fax: 301–847–8640, *renan.bonnel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Large volumes of data in the context of the health care industry have the potential to provide additional information related to medication use, which may affect the benefit-risk assessment of medicines in general and pediatric medicines in particular. Since pediatric pharmacoepidemiologic studies tend to enroll fewer patients than adult studies, additional information may be needed to better understand the safety and efficacy of use of these drugs in children. ''Big Data'', including forms of real world evidence that may involve large and complex data sets, may be particularly useful as a supplement to traditional studies. Supplementary information may include additional clinical trial data, registry data, and electronic health record information.

II. Topics for Discussion at the Public Workshop

In this workshop, FDA will gather information on the latest developments in ''Big Data'' from the perspective of a number of stakeholders and expand the conversation to include the utility and challenges associated with the use of ''Big Data'' in the pediatric setting. Day 1 will focus on national and international uses of ''Big Data'' in health care. Day 2 will focus on ''Big Data'' utility in the pediatric setting, including specific challenges associated with pediatric data.

III. Participation in the Public Workshop

Registration: Persons interested in attending this workshop must register online at: *https://www.eventbrite.com/e/public-workshop-advancing-the-development-of-pediatric-therapeutics-adept-application-of-big-data-tickets-32470264435* by August 22, 2017. For those without internet access, please contact Renan A. Bonnel (see **FOR FURTHER INFORMATION CONTACT**) to register.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 22, 2017. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants.

Registration information, the agenda, and additional background materials can be found at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm545847.htm.*

If you need special accommodations due to a disability, please contact Renan A. Bonnel (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast.

September 18: Login URL: *https://event.webcasts.com/starthere.jsp?ei=1144352* (morning session).

After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (*Note:* the link for the afternoon session is different from the morning session): Login URL: *https://event.webcasts.com/starthere.jsp?ei=1144354* (afternoon session).

September 19: Login URL: *https://event.webcasts.com/starthere.jsp?ei=1144356* (morning session).

After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (*Note:* the link for the afternoon session is different from the morning session): Login URL: *https://event.webcasts.com/starthere.jsp?ei=1144357* (afternoon session).

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 Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites 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 office (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will be available on the internet at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm545847.htm.*

Dated: August 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17783 Filed 8–22–17; 8:45 am]

BILLING CODE 4164–01–P