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 has been approved under 0910–0014; the collection of information in 21 CFR part 314 has been approved under 0910–0001; the collection of information in 21 CFR part 601 has been approved under 0910–0338; and the collection of information for applications submitted under section 351(k) of the PHS Act has been approved under 0910–0719. In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.*

Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05626 Filed 3–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advancing the Development of Pediatric Therapeutics: Successes and Challenges of Performing Long-Term Pediatric Safety Studies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics (OPT) and Center for Drug Evaluation and Research are announcing a 2-day public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT): Successes and Challenges of Performing Long-Term Pediatric Safety Studies.'' The purpose of this 2-day public workshop is for FDA to have an open discussion with experts in the field examining the need and path forward for long-term pediatric safety studies. Day 1 of the public workshop will focus on an exposition of the successes and challenges of long-term safety studies in children. Day 2 of the public workshop will focus on suggestions for the future on study design and implementation of long-term safety studies in children. Viewpoints of patient representatives of children with chronic conditions and industry will be included.

DATES: The public workshop will be held on April 13 and 14, 2016, from 8 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—Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

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, email: *renan.bonnel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Medical product safety studies in children are usually performed for 6 months or less. In children, measurement of long-term outcomes is particularly challenging since, compared to adults, children are undergoing dramatic growth and developmental changes. This 2-day public workshop will focus on the challenges of long-term follow-up in children receiving medical products. The first day of the public workshop will focus on the problems or barriers, including; challenges with study design, data capture, infrastructure, and endpoints. Viewpoints of parents and industry will be represented. The second day of the public workshop will include panel discussions to propose solutions to the problems posed on day one and to discuss the epidemiological challenges posed by the collection of data on different types of adverse events. On both days of the public workshop there will be a certain amount of time on the agenda for attendee questions or comments.

II. Participation in the Public Workshop

Registration: There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at: *http://pediatricsafety.eventbrite.com* before April 7, 2016. For those without Internet access, please contact Renan A. Bonnel (see **FOR FURTHER INFORMATION CONTACT**) to register. In the event that a minimum number of participants have not registered, the workshop will be postponed. Registered participants will be notified of any change. Onsite registration will be available if seating permits it. Registration information, the agenda, and additional background materials can be found at *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm477639.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.

Web cast: The live Web cast on April 13, 2016, will be available at: *https://event.webcasts.com/starthere.jsp?ei=1093258.* 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 that it is different from the morning's session): *https://event.webcasts.com/starthere.jsp?ei=1093259.* On April 14, 2016, the live Web cast will be available at: *https://event.webcasts.com/starthere.jsp?ei=1093263.* 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 that it is different from the morning's session): *https://event.webcasts.com/starthere.jsp?ei=1093265.* The Web cast will only be for listening and there will not be an opportunity for Web cast participants to speak.

The videocast will be posted after the workshop at *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm477639.htm.*

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information. The Freedom of Information address is available on the Agency's Web site at

http://www.fda.gov. Send faxed requests to 301–827–9267.

Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05621 Filed 3–11–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

The Fifth Annual Food and Drug Administration-International Society for Pharmaceutical Engineering Quality Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in co-sponsorship with the International Society for Pharmaceutical Engineering (ISPE), is announcing a meeting entitled ''Fifth Annual FDA–ISPE Quality Conference.'' The purpose of the meeting is to discuss manufacturing, compliance, and management practices that create, implement, and sustain a culture of high quality and result in reliable pharmaceutical and biologic products that support patient health.

DATES: The meeting will be held on June 6, 7, and 8, 2016, from 8:30 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan Krys, ISPE, 7200 Wisconsin Ave., Suite 305, Bethesda, MD 20814, 301–364–9202, FAX: 240–204–6024, email: *skrys@ispe.org,* or Sau (Larry) Lee, 301–796–2905, email: *Sau.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: ISPE is an association of engineers, scientists, manufacturing, quality, and industrial professionals involved in the development, manufacture, quality control, and regulation of pharmaceuticals and related products. This co-sponsored meeting facilitates discussion and problem solving around technical, quality, compliance, and other manufacturing issues.

Registration: There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of programming and facilities. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at *http://www.ispe.org/events.* FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**. The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives:	
ISPE Members	$1,895 (early-bird); $2,095 (onsite).
Non-members	$2,275 (early-bird); $2,475 (onsite).
Academic	$1,425 (early-bird); $1,575 (onsite).
Government	$700 (early-bird); $700 (onsite).

Accommodations: Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Bethesda North Marriott Hotel & Conference Center in Bethesda, MD are eligible for a reduced rate of $209 USD, not including applicable taxes. To receive the reduced rate, contact the Bethesda North Marriott Hotel (1–301–822–9200 or 1–800–859–8003) and identify yourself as an attendee of the meeting. If you need special accommodations due to a disability, please contact Susan Krys at least 7 days in advance.

Transcripts: We expect that transcripts will be available approximately 30 days after the meeting. A transcript will be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* Send faxed requests to 301–827–9267.

Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05627 Filed 3–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 25, 2016, from 8 a.m. to 5:30 p.m. This meeting is a reschedule of a postponed meeting announced in the **Federal Register** of December 18, 2015 (80 FR 79047), originally scheduled for January 22, 2016.

Location: College Park Marriott Hotel and Conference Center, Chesapeake Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301–985–7300.

Contact Person: 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 *http://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.

Agenda: The committee will discuss new drug application (NDA) 206488,