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Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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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 Kryz, ISPE, 7200 Wisconsin Ave., Suite 305, Bethesda, MD 20814, 301-364-9202, FAX: 240-204-6024, email: skryz@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 Kryz 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.

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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,