DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Federal Register Notice, 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:

<table>
<thead>
<tr>
<th>Category</th>
<th>Cost</th>
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<tbody>
<tr>
<td>ISPE Members</td>
<td>$1,895 (early-bird); $2,095 (onsite).</td>
</tr>
<tr>
<td>Non-members</td>
<td>$2,275 (early-bird); $2,475 (onsite).</td>
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<tr>
<td>Academic</td>
<td>$1,425 (early-bird); $1,575 (onsite).</td>
</tr>
<tr>
<td>Government</td>
<td>$700 (early-bird); $700 (onsite).</td>
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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, 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.

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,