

<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]

**BILLING CODE 4164-01-P**

**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](mailto:skryz@ispe.org), or Sau (Larry) Lee, 301-796-2905, email: [Sau.Lee@fda.hhs.gov](mailto: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.

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](mailto: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,

eteplirsén injection for intravenous infusion, sponsored by Sarepta Therapeutics, Inc., for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

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 <http://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. Written submissions may be made to the contact person on or before April 11, 2016. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 2:40 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 April 1, 2016. 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 April 4, 2016.

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 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 <http://www.fda.gov/AdvisoryCommittees/>

*About Advisory Committees/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: March 9, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-05683 Filed 3-10-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than April 13, 2016.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

#### Information Collection Request Title: Bureau of Health Workforce Performance Data Collection

*OMB No. 0915-0061—Revision*

*Abstract:* Over 40 Bureau of Health Workforce (BHW) programs award grants to health professions schools and training programs across the United States to develop, expand, and enhance

training, and to strengthen the distribution of the health workforce. These programs are authorized by the Public Health Service Act (42 U.S.C. 201 *et seq.*), specifically Titles III, VII, and VIII. Performance information regarding these programs is collected in the HRSA Performance Report for Grants and Cooperative Agreements (PRGCA). Data collection activities consisting of an annual progress and annual performance report satisfy statutory and programmatic requirements for performance measurement and evaluation (including specific Title III, VII and VIII requirements), as well as Government Performance and Results Act (GPRA) requirements. The performance measures were last revised in 2013 to ensure they addressed programmatic changes, met evolving program management needs, and responded to emerging workforce concerns—especially as a result of the changes in the Affordable Care Act (Pub. L. 111-148). As these revisions were successful, BHW will continue to use the same progress and performance forms. BHW is reducing the reporting burden by eliminating the semi-annual performance report and moving to annual progress and performance reporting.

*Need and Proposed Use of the Information:* The purpose of the data collection is to analyze and report grantee training activities and education, identify intended practice locations, and report outcomes of funded initiatives. Data collected from these grant programs also provide a description of the program activities of approximately 1,700 reporting grantees to better inform policymakers on the barriers, opportunities, and outcomes involved in health care workforce development. The measures focus on five key outcomes: (1) Increasing the workforce supply of diverse well-educated practitioners, (2) increasing the number of practitioners that practice in underserved and rural areas, (3) enhancing the quality of education, (4) increasing the recruitment, training, and placement of under-represented groups in the health workforce, and (5) supporting educational infrastructure to increase the capacity to train more health professionals.

*Likely Respondents:* Respondents are awardees of BHW health professions grant programs.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize