

Fax Number: (202) 395-5806 OR  
Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov)

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:**

Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Quality of Care Complaint Form; *Use:* In accordance with Section 1154(a)(14) of the Social Security Act, Quality Improvement Organizations (QIOs) are required to conduct appropriate reviews of all written complaints submitted by beneficiaries concerning the quality of care received. The Medicare Quality of Care Complaint Form will be used by Medicare beneficiaries to submit quality of care complaints. This form will establish a standard form for all beneficiaries to utilize and ensure pertinent information is obtained by QIOs to effectively process these complaints. *Form Number:* CMS-10287 (OMB control number: 0938-1102); *Frequency:* Occasionally; *Affected*

*Public:* Individuals and Households; *Number of Respondents:* 3,500; *Total Annual Responses:* 3,500; *Total Annual Hours:* 583. (For policy questions regarding this collection contact Winsome Higgins at 410-786-1835.)

Dated: November 9, 2016

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2016-27455 Filed 11-15-16; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-3744]

**Site Visit Training Program for Office of Pharmaceutical Quality Staff; Information Available to Industry**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Center for Drug Evaluation and Research (CDER) in the Food and Drug Administration (FDA) is announcing the 2017 CDER Office of Pharmaceutical Quality (OPQ) Staff Experiential Learning Site Visit Program. The purpose of this document is to invite pharmaceutical companies interested in participating in this program to submit a site visit proposal to CDER's OPQ.

**DATES:** Submit either an electronic or written proposal to participate in this program by January 17, 2017. See section IV of this document for information on what to include in such proposals.

**FOR FURTHER INFORMATION CONTACT:**

Janet Wilson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4642, Silver Spring, MD 20993-0002, 240-402-3969, email: [CDEROPQSiteVisits@fda.hhs.gov](mailto:CDEROPQSiteVisits@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

A critical part of the commitment by CDER to make safe and effective high-quality drugs available to the American public is gaining an understanding of all aspects of drug development and a drug's commercial life cycle, including the variety of drug manufacturing operations. To support this commitment, CDER has initiated various training and development programs, including the 2017 OPQ Staff Experiential Learning Site Visit

Program. This site visit program is designed to offer experiential and firsthand learning opportunities that will provide OPQ staff with a better understanding of the pharmaceutical industry and its operations, as well as of the challenges that impact a drug's development program and commercial life cycle. The goal of these visits is to provide OPQ staff exposure to the drug development and manufacturing processes in industry; therefore, a tour of pharmaceutical company facilities is an integral part of the program.

**II. The Site Visit Program**

In this site visit program, groups of OPQ staff—who have experience in a variety of backgrounds, including science, statistics, manufacturing, engineering and testing—will observe operations of commercial manufacturing, pilot plants, and testing over a 1- to 2-day period. To facilitate the learning process for OPQ staff, overview presentations by industry related to drug development and manufacturing may be provided, which may allow the participating sites to benefit by having an opportunity to showcase their technologies and manufacturing processes.

OPQ encourages companies engaging in the development and manufacturing of both drug substances and drug products to respond. However, please note that this site visit program is not intended to supplement or to replace a regulatory inspection, e.g., a preapproval inspection, pre-license inspection or a surveillance inspection. OPQ staff participating in this program will grow professionally by gaining a better understanding of current industry practices, processes, and procedures.

Although observation of all aspects of drug development and production would be beneficial to OPQ staff, OPQ has identified a number of areas of particular interest to its staff. The following list identifies some of these areas but is not intended to be exhaustive or to limit industry response:

- Drug products and active pharmaceutical ingredients
- Solutions, suspensions, emulsions, and semisolids
- Sustained, modified, and immediate release formulations
- Drug-device combination products, particularly inhalation, transdermal, iontophoretic, and implant formulations
- Biotechnology products
- Design, development, manufacturing, and controls
- Engineering controls for aseptic formulations
- Unique delivery technologies

- Hot melt extrusion processes
- Soft-gel encapsulation processes
- Lyophilization processes
- Blow-Fill-Seal and isolators
- Spray-drying processes
- Process analytical technology and Real Time Release Testing
- Emerging technologies
- Continuous manufacturing
- 3-dimensional printing
- Nanotechnology

### III. Site Selection

Selection of potential facilities will be based on the priorities developed for OPQ staff training, the facility's current regulatory status with FDA, and on consultation with the appropriate FDA district office. All travel expenses associated with this program will be the responsibility of OPQ; therefore, selection will be based on the availability of funds and resources for the fiscal year. OPQ will not provide financial compensation to the pharmaceutical site as part of this program.

### IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site visit program should respond by submitting a proposal directly to Janet Wilson (see the **DATES** and **FOR FURTHER INFORMATION CONTACT** sections of this document for more information). To aid in OPQ's site selection, your proposal should include the following information:

- A contact person
- Site visit location(s)
- Facility Establishment Identifier and DUNS numbers, as applicable
- Maximum number of OPQ staff that can be accommodated during a site visit, and
- A sample agenda outlining the proposed learning objectives and associated activities for the site visit

Proposals submitted without this minimum information will not be considered. Based on response rate and type of responses, OPQ may or may not consider alternative pathways to meeting our training goals.

Dated: November 9, 2016.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2016-27454 Filed 11-15-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee to the Director, National Institutes of Health.  
*Date:* December 8, 2016.

*Time:* 9:00 a.m. to 5:15 p.m.

*Agenda:* NIH Director's Report, ACD Working Group Reports.

*Place:* National Institutes of Health, Building 31, 6th Floor Conference Room 6C, 31 Center Drive, Bethesda, MD 20892.

*Date:* December 9, 2016.

*Time:* 9:00 a.m. to 12:00 p.m.

*Agenda:* Other business of the Committee.

*Place:* National Institutes of Health, Building 31, 6th Floor Conference Room 6C, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301-496-4272, [Woodgs@od.nih.gov](mailto:Woodgs@od.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Office of the Director, National Institutes of Health, home page: <http://acd.od.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate

Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 9, 2016.

**Anna Snouffer**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-27463 Filed 11-15-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

*Date:* November 30–December 1, 2016.

*Time:* 12:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Chee Lim, Ph.D., Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, Bethesda, MD 20892, 301-435-1850, [limc4@csr.nih.gov](mailto:limc4@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular and Respiratory Special Emphasis Panel.

*Date:* December 7, 2016.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Olga A Tjurmina, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 451-1375, [ot3d@nih.gov](mailto:ot3d@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Sciences.

*Date:* December 7–8, 2016.