accounting firm to review the adequacy of the PDUFA adjustment for changes in workload (hereafter referred to as the workload adjuster).

The workload adjuster was introduced in PDUFA III to allow for FDA to augment the total user fee revenue amount each fiscal year (after adjusting for inflation) to account for changes in workload volume in the human drug application review process. Workload volume is measured by the changes in the number of new drug applications and biologics license applications (NDAs/BLAs), active commercial investigational new drugs (INDs), efficacy supplements, and manufacturing supplements submitted to the human drug review program during the most recent 5-year period.

In PDUFA IV, the workload adjuster was expanded to account for the workload complexity (known as the adjustment for changes in review activities) associated with the review of NDAs/BLAs and active commercial INDs. The NDA/BLA complexity is measured by changes in the number of labeling supplements, annual report reviews, and NDA/BLA meetings per NDA/BLA. IND complexity is measured by changes in the number of special protocol assessments and IND meetings per active commercial IND.

As part of the PDUFA IV recommendations, FDA committed to an evaluation of the adjustment for changes in review activities by an independent accounting firm. The study, conducted by Deloitte & Touche, LLP, found that the adjustment methodology used by FDA reasonably captures changes in the workload complexity for reviewing human drug applications under PDUFA IV. While the FY 2009 evaluation concluded that the adjustment methodology was reasonable at that point in time, the complexity of new drug applications and FDA's regulatory responsibilities are constantly evolving. Moreover, the complexity component of the PDUFA IV workload adjuster was formulated before the enactment of the Food and Drug Administration Amendments Act (FDAAA). Thus, the workload adjuster does not account for new and significant review activities required by FDAAA, such as risk evaluation and mitigation strategies, safety labeling changes, advisory committee meetings, and post-market safety requirements, among others.

Given the dynamic nature of drug products and FDA's regulatory responsibilities, FDA committed to periodic reassessments of the workload adjuster in PDUFA V to ensure that it is achieving its intended role of adjusting the user fee revenues to reflect actual changes in FDA's workload volume and complexity.

The PDUFA V commitment letter instructs FDA to contract with an independent accounting or consulting firm to conduct two assessments of the workload adjuster. This first assessment (to examine the performance of the workload adjuster since FY 2009) was just completed. The independent accounting or consulting firm is required to submit reports based on their assessments. The reports will evaluate whether the workload adjuster reasonably represents actual changes in workload volume and complexity and will present recommendations to discontinue, retain, or modify any elements of the adjustment. After review of the reports and receipt of public comments, FDA, if warranted, may implement appropriate changes to the methodology. If FDA adopts changes to the methodology based on the first report, the changes are effective the fiscal year after FDA adopts the changes and each subsequent fiscal year.

FDA is seeking public comment now on the first assessment of the PDUFA Workload Adjuster, available at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee.*

II. Comments

Interested persons may submit either electronic comments regarding the Analysis to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: April 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10626 Filed 5–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Food and Drug Administration/International Society for Pharmaceutical Engineering Co-Sponsorship Educational Workshop: Redefining the 'C' in CGMP (Current Good Manufacturing Practices): Creating, Implementing, and Sustaining a Culture of Quality

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), in co-sponsorship with the International Society of Pharmaceutical Engineering (ISPE), is announcing a conference entitled ''Redefining the 'C' in CGMP: Creating, Implementing and Sustaining a Culture of Quality'' Pharmaceutical Quality System (ICH Q10) Conference.

The conference will span 3 days and is dedicated to teaching the principles of CGMP, reaping the benefits that come from establishing and maintaining a state of control, implementing continual improvement, enhancing regulatory compliance, and meeting quality objectives every day. The conference will take place in Baltimore, MD, and will draw on the best industry and regulator contributors on this topic.

Date and Time: The conference will be held on June 11, 2013, from 8:30 a.m. to 5 p.m.; June 12, 2013, from 8 a.m. to 5 p.m.; and June 13, 2013, from 8 a.m. to 4:30 p.m.

Location: The event will be held at the Renaissance Baltimore Harborplace Hotel, 202 East Pratt St., Baltimore, MD 21201, 1–800–535–1201.

Contact Person: Nancy Berg, President, International Society for Pharmaceutical Engineering, 600 North Westshore Blvd., suite 900, Tampa, FL 33609, Web site: *http://www.ISPE.org/CGMP.*

Conference attendees are responsible for their own accommodations.

Registration: You are encouraged to register at your earliest convenience. The ISPE registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted to the conference will receive confirmation. Registration will close after available conference space is filled. Onsite registration will be available on a space available basis on the day of the

public conference beginning at 7 a.m. on June 11, 2013. The cost of registration is as follows:

ISPE Member	$1,545 (prior to May 13); $1,745 (after May 13 and onsite).
ISPE Nonmember	$1,905 (prior to May 13); $2,115 (after May 13 and onsite).
ISPE New Member	$1,814 (prior to May 13); $2,014 (after May 13 and onsite).
Federal Government Employee registering prior to/after May13	$500.
FDA Planning Committee Members and Invited Speakers	(free) Fee Waived.
ISPE Active, Functional and Program Committee Members	$1,005 (prior and after May 13).
Student (prior to/after May 13)	$200.
Individuals from Academia/Emerging Economy	$1,005 (prior to May 13); $1,135 (after May 13 and onsite).

Registration instructions: To register, please submit your name, affiliation, mailing address, phone number, fax number, and email address, along with a check or money order payable to ''ISPE.'' To register via the Internet, go to the ISPE Web site, *www.ISPE.org,* to confirm the prevailing registration fees.

Dated: May 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10651 Filed 5–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

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 meeting.

The meeting 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; VH–BST Member Conflicts.

Date: May 21, 2013.

Time: 1:00 p.m. to 3:00 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*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 30, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10570 Filed 5–3–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trials Units for NIAID Networks.

Date: May 31, 2013.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 1202, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Roberta Binder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, Room 3130, Bethesda, MD 20892–7616, 301–496–7966, *rbinder@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trials Unit for NIAID Networks.

Date: July 2, 2013.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 3130, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Roberta Binder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, Room 3130, Bethesda, MD 20892–7616, 301–496–7966, *rbinder@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 30, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10575 Filed 5–3–13; 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.