Act to expand the situations in which FDA may order postmarket surveillance and allow longer surveillance periods in certain circumstances. This guidance document is intended to assist device manufacturers subject to a section 522 postmarket surveillance order by providing an overview of section 522 of the FD&C Act, procedural information on how to fulfill section 522 obligations, and recommendations on the format, content, and review of postmarket surveillance study submissions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Procedures for Handling Section 522 Postmarket Surveillance Studies.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Procedures for Handling Section 522 Postmarket Surveillance Studies'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1754 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: August 10, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20727 Filed 8–15–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

2011 Parenteral Drug Association/Food and Drug Administration Joint Public Conference; Quality and Compliance in Today's Regulatory Enforcement Environment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), in cosponsorship with Parenteral Drug Association (PDA), is announcing a public conference entitled ''Quality and Compliance in Today's Regulatory Enforcement Environment.'' The conference will span 2½ days and cover current issues affecting the industry as well as explore strategies and approaches for ensuring conformance with regulations to facilitate the development and continuous improvement of safe and effective medical products. The conference establishes a unique forum to discuss the foundations, emerging technologies and innovations in regulatory science, as well as the current quality and compliance areas of concerns. Meeting participants will hear from FDA and industry speakers about the requirements and best practices to consider while implementing robust quality systems in order to deliver the best quality product.

Date and Time: The public conference will be held on September 19, 2011, from 7 a.m. to 6 p.m.; September 20, 2011, from 7:30 a.m. to 6:15 p.m.; and September 21, 2011, from 7:30 a.m. to 12:15 p.m.

Location: The public conference will be held at the Renaissance Hotel, 999 Ninth St., NW., Washington, DC 20001, 202–898–9000, FAX: 202–289–0947.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814, 301–656–5900, FAX: 301–986–1093, e-mail: info@pda.org.

Accommodations: Attendees are responsible for their own accommodations. To make reservations at the Renaissance Hotel at the reduced conference rate, contact the Renaissance Hotel (see *Location*)—cite the meeting code ''PDA.'' Room rates are: Single: $288, plus 14.5% state and local taxes and Double: $288, plus 14.5 percent state and local taxes. Reservations can be made on a space and rate availability basis.

Registration: Attendees are encouraged to register at their earliest convenience. The PDA registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted for the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space available basis on each day of the public conference beginning at 7 a.m. on September 19, 2011. The cost of registration is as follows:

COST OF REGISTRATION

Affiliation	Fee
PDA Members	$1,895
NonMembers	2,144
PDA Member Government/Health Authority	700
NonMember Government/Health Authority	800
PDA Member Academic	700
NonMember Academic	780
PDA Member Students	280
NonMember Students	310

Please visit PDA's Web site: *http://www.pda.org/pdafda2011* to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Wanda Neal (see *Contact*), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and e-mail address, along with a check or money order payable to ''PDA.'' Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814. To register via the

Internet, go to PDA's Web site: *http://www.pda.org/pdafda2011.*

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see *Contact*).

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA joint public conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Accountability in a Global Environment—Enforcement and Supply Chain
- Office of International Programs 101 & Foreign Inspections
- International Conference on Harmonization Q11
- New Regulations—Status Update
- First Cycle Review
- Drug Safety
- Good Inspection Practices—Domestic
- Process Validation
- Emerging Regulations for Positron Emission Tomography
- FDA/Pharmaceutical Inspection Co-operation Scheme
- Standards
- International Compliance Update
- Good Manufacturing Practice Life Cycle
- Supply Chain

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: August 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20791 Filed 8–15–11; 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 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

Dates: September 9, 2011

Time: 1 p.m. to 4 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: Yuanna Cheng, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301)435–1195, *Chengy5@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Social Science and Population Studies: Second Panel.

Dates: September 19, 2011.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Suzanne Ryan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

(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: August 9, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–20829 Filed 8–15–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; T35 Training Grant in Pediatric Respiratory, Sleep, and Transfusion Medicine.

Date: September 7, 2011.

Time: 2 p.m. to 4 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: Stephanie L Constant, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 10, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–20845 Filed 8–15–11; 8:45 am]

BILLING CODE 4140–01–P