

or other forms of information technology to minimize the information collection burden.

**Terry S. Clark,**

*Deputy Information Collection Clearance Officer.*

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**BILLING CODE 4150-28-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review**

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to [(FOA) GH15-001, Conducting Public Health Research in Kenya, Funding Opportunity Announcement.

*Time and Date:* 12:00 p.m.—5:00 p.m., April 1, 2015 (Closed).

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters for Discussion:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “Conducting Public Health Research in Kenya, FOA GH15-001”.

*Contact Person for More Information:* Hylan Shoob, Scientific Review Officer, Center for Global Health (CGH) Science Office, CGH, CDC, 1600 Clifton Road, NE., Mailstop D-69, Atlanta, Georgia 30033, Telephone: (404) 639-4796.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and

other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-0001]

**2015 Parenteral Drug Association/Food and Drug Administration Joint Conference**

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

**ACTION:** Notice of public conference.

The Food and Drug Administration (FDA), is announcing a public conference, to be held in co-sponsorship with the Parenteral Drug Association (PDA), entitled “Mission Possible: Patient-Focused Manufacturing, Quality, and Regulatory Solutions.” The conference will cover current issues affecting the industry as well as explore strategies 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 28, 2015,

from 7 a.m. to 7:30 p.m.; September 29, 2015, from 7 a.m. to 9:30 p.m.; and September 30, 2015, from 7 a.m. to 12:30 p.m.

*Location:* The public conference will be held at the Renaissance Washington Hotel, 999 Ninth Street 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 150, Bethesda, MD 20814, 301-656-5900, ext. 111, FAX: 301-986-1093, email: *info@pda.org*; or Ken Nolan, Office of Communications, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8629, email: *kenneth.nolan@fda.hhs.gov*.

*Accommodations:* Attendees are responsible for their own accommodations. To make reservations, contact the Renaissance Washington Hotel (see *Location*) and reference “the 2015 PDA/FDA Joint Regulatory Conference” to receive the PDA group rate. Room rates are: Single: \$305 plus 14.5 percent State and local taxes. Requests will be processed on a first-come, first-served 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 beginning at 1 p.m. on September 27, 2015, and at 7 a.m. from September 28 through 30, 2015. The cost of registration is as follows:

**COST OF REGISTRATION**

Affiliation	Before July 19, 2015	July 19–August 18, 2015	After August 18, 2015
<b>Premier Package (Includes Conference and Workshop Registration)</b>			
Member .....	\$3,240	\$3,490	\$3,740
Nonmember .....	3,599	3,849	4,099
<b>Conference Only</b>			
Member .....	1,895	2,095	2,295
Nonmember .....	2,154	2,354	2,554
Government/Health Authority Member .....	700	700	700
Government/Health Authority Nonmember* .....	800	800	800
Academic Member .....	700	700	700
Academic Nonmember* .....	800	800	800

## COST OF REGISTRATION—Continued

Affiliation	Before July 19, 2015	July 19–August 18, 2015	After August 18, 2015
Student Member .....	280	280	280
Student Nonmember* .....	310	310	310

\* For this member type, online registration is not available and must be faxed in.

Please visit PDA's Web site:

[www.pda.org/pdafda2015](http://www.pda.org/pdafda2015) 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 email address, along with a check or money order payable to "PDA." Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 150, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site: [www.pda.org/pdafda2015](http://www.pda.org/pdafda2015).

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 Regulatory 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 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:

- Product Quality
- Data Integrity

- Breakthrough Therapies
- Regulatory Challenges and Opportunities
- Lifecycle Management
- Clinically Relevant Specifications
- Food and Drug Administration Safety and Innovation Act
- Quality Metrics/Quality Culture
- Manufacturing of the Future With Submissions
- Continuous Verification and Validation
- Continuous Manufacturing
- "Fishbowl" Role Play
- Quality Systems
- Contract Manufacturing Organizations
- Maturity of Quality Systems
- Investigations
- Case Studies for Quality
- Quality Submissions
- Prescription Drug User Fee Act
- Risk-Based Control Strategies
- Supply Chain
- Quality Risk Management Systems
- Drug Shortages
- Customer Complaint Reviews and Trending
- Human Factors
- Office of Pharmaceutical Quality and Program Alignment Group
- Patient Perspective
- Compliance Update
- Center Initiatives—Regulatory Submission Update

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: March 4, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0253]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Drug Experience Reporting and Recordkeeping Biological Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's postmarketing adverse drug experience reporting and recordkeeping requirements.

**DATES:** Submit either electronic or written comments on the collection of information by May 11, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal