

agencies, and the private sector to: Improve the effectiveness and efficiency of programs; and foster sound growth and development of children and their families.

The Division provides guidance, analysis, technical assistance and oversight in ACF on: strategic planning and performance measurement for all ACF programs, including child and family development; statistical, policy and program analysis; surveys, research and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and demonstration findings; and application of emerging technologies to improve the effectiveness of programs and service delivery.

The Division conducts, manages, and coordinates major cross-program, leading-edge research, demonstration, and evaluation studies; develops policy-relevant research priorities; and manages and conducts statistical, policy, and program analyses related to children and families. Division staff also provides consultation, coordination, direction and support for research activities related to children and families across ACF programs.

IV. Under Chapter KM, Office of Planning, Research and Evaluation, add KM.20 Functions, Paragraph D as follows:

D. The Division of Family Strengthening, in cooperation with ACF programs and others, works with Federal counterparts, States, community agencies, and the private sector to: Improve the effectiveness and efficiency of programs; assure the protection of children, youth, and other vulnerable populations; strengthen families; and foster sound growth and development of children, youth and their families.

The Division provides guidance, analysis, technical assistance and oversight in ACF on: child, youth and family development; child safety; statistical, policy and program analysis; surveys, research and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and demonstration findings; and application

of emerging technologies to improve the effectiveness of programs and service delivery.

The Division conducts, manages, and coordinates major cross-program, leading-edge research, demonstration, and evaluation studies; develops policy-relevant research priorities; and manages and conducts statistical, policy, and program analyses related to strengthening families. Division staff also provides consultation, coordination, direction and support for research activities related to strengthening families across ACF programs.

Dated: July 10, 2012.

**George H. Sheldon,**  
*Acting Assistant Secretary for Children and Families.*

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**BILLING CODE 4184-79-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0001]

**2012 Parenteral Drug Association/Food and Drug Administration Joint Regulatory Conference; Compliance Through Quality Systems: Implementing and Advancing a Sustainable Global Quality Culture**

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

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA), in cosponsorship with Parenteral Drug Association (PDA), is announcing a public conference entitled “Compliance Through Quality Systems: Implementing and Advancing a Sustainable Global Quality Culture.” The conference will 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 10, 2012, from 7 a.m. to 6 p.m.; September 11, 2012, from 7:30 a.m. to 6:15 p.m.; and September 12, 2012, from 7:30 a.m. to 12:15 p.m.

**Location:** The public conference will be held at the Baltimore Marriott Waterfront Hotel, 700 Aliceanna St., Baltimore, MD 21202, 410-385-3000, Fax: 410-895-1900.

**Contact:** Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 200, Bethesda, MD 20814, 301-656-5900, ext. 111, Fax: 301-986-1093, email: [info@pda.org](mailto:info@pda.org).

**Accommodations:** Attendees are responsible for their own accommodations. To make reservations at the Baltimore Marriott Waterfront Hotel at the reduced conference rate, contact the Baltimore Marriott Waterfront Hotel (see *Location*)—cite the meeting code “PDA.” Room rates are: Single: \$229, plus 15.5 percent state and local taxes and Double: \$229, plus 15.5 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 10, 2012. The cost of registration is as follows:

TABLE 1—COST OF REGISTRATION

Affiliation	Through August 10, 2012	After August 10, 2012
Member .....	\$1,700	\$1,900
Nonmember .....	1,949	2,149
Government/Health Authority Member .....	530	530
Government/Health Authority Nonmember <sup>1</sup> .....	700	700
Academic Member .....	700	700
Academic Nonmember <sup>1</sup> .....	800	800
Student Member .....	280	280

TABLE 1—COST OF REGISTRATION—Continued

Affiliation	Through August 10, 2012	After August 10, 2012
Student Nonmember <sup>1</sup> .....	310	310

<sup>1</sup> Applicable nonmember rates.

Please visit PDA's Web site: <http://www.pda.org/pdafda2012> 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 200, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site: <http://www.pda.org/pdafda2012>.

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 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:

- Regulatory Submission and Meetings

- Quality Risk Management Implementation
- Manufacturing in the Future
- Quality Systems
- Regulatory Considerations During Development
- Cell Therapy Innovations
- Life Cycle Management
- Process Validation
- Validation FDA Guidance
- Challenges of Contract Manufacturing Organizations
- Contract Agreements
- Drug Safety
- Emerging Active Pharmaceutical Ingredients (API) Regulations
- Investigations
- Emerging API Regulations
- User Fees
- Excipient Best Practices
- Good Manufacturing Practices
- Foreign Inspections Findings (Inspectional Readiness)
- Combination Products and Companion Diagnostics

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 1, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Notice of Availability of Draft Policy Document for Comment

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** This is a Notice of Availability and request for comments on a draft

Agency Guidance ("Policy Information Notice" (PIN)). The draft PIN provides clarification on the sliding fee discount program and related requirements for federally-funded health centers and Federally Qualified Health Center (FQHC) Look-Alikes. The draft PIN, "Clarification of Sliding Fee Discount Program Requirements," is available on the Internet at <http://www.bphc.hrsa.gov/policiesregulations/policies/draftsforcomment.html>.

**DATES:** Comments must be received by the close of business on September 28, 2012.

**ADDRESSES:** Comments should be submitted to [OPPDSFPIN@hrsa.gov](mailto:OPPDSFPIN@hrsa.gov) by the close of business on September 28, 2012.

**SUMMARY:** HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Health Center Program. Therefore, we are requesting comments on the PIN referenced above. Comments will be reviewed and analyzed, and a final PIN, along with a summary and general response to the comments, will be published as soon as possible after the deadline for receipt of comments.

Background: HRSA provides grants to eligible health centers under Section 330 of the Public Health Service Act (PHS Act) to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. In 2011, grants helped fund approximately 1,200 health center grantees, which provided services at more than 8,500 health care delivery sites and served more than 20.2 million people. There are also approximately 100 FQHC Look-Alikes. As described in section 1861(aa)(4) and section 1905(l)(2)(B) of the Social Security Act, FQHC Look-Alikes do not receive Federal funding under Section 330 of the PHS Act. However, in order to receive the FQHC Look-Alike designation and benefits, FQHC Look-Alikes must meet the statutory, regulatory, and policy requirements for Health Centers Programs under Section 330.

A key requirement of the Health Center Program is for a health center to establish a "sliding fee discount