

## ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Average annual burden hours
#3 Program Leadership/Managers/Supervisors Interview Guide .....	46	1	2	92	31
#3 Instructional Staff Interview Guide .....	58	1	2	116	39
#3 Case Managers/Advisor Interview Guide .....	50	1	2	100	33
#3 Partners Interview Guide .....	54	1	2	108	36
#4 Case Managers/Advisors Online Survey .....	90	1	0.5	45	15
#5 Manager/Supervisor Online Survey .....	43	1	0.5	22	7
#6 Instructional Staff Online Survey .....	136	1	0.5	68	23
#7 Study Participant Interview Guide .....	210	2	2.083	875	292
#7 Study Participant Check-in Call .....	210	1	0.16	34	11
Total Burden Hours: New Collection .....				9,380	3,127

**Additional Information:** Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Email:* [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Steven M. Hanmer,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

#### 2013 Parenteral Drug Association/Food and Drug Administration Joint Regulatory Conference: Driving Quality and Compliance Throughout the Product Life Cycle in a Global Regulatory Environment

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

**ACTION:** Notice of public conference.

The Food and Drug Administration (FDA), in co-sponsorship with the Parenteral Drug Association (PDA), is announcing a public conference titled “Driving Quality and Compliance Throughout the Product Life Cycle in a Global Regulatory Environment.” 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 16, 2013, from 7 a.m. to 6 p.m.; September 17, 2013, from 7:30 a.m. to 6:15 p.m.; and September 18, 2013, from 7:30 a.m. to 12:15 p.m.

**Location:** The public conference will be held at the Renaissance Washington Hotel, 999 9th 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, ext. 111, FAX: 301-986-1093, email: [info@pda.org](mailto:info@pda.org) or Ken Nolan, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5314, Silver Spring, MD 20993, 301-796-8629, email: [kenneth.nolan@fda.hhs.gov](mailto:kenneth.nolan@fda.hhs.gov).

**Accommodations:** Attendees are responsible for their own accommodations. To make reservations at the Renaissance Washington Hotel at the reduced conference rate, contact the Renaissance Washington Hotel (see **Location**)—cite the meeting code “PDA.” Room rates are: Single or Double: \$299, 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 16, 2013. The cost of registration is as follows:

## COST OF REGISTRATION

Affiliation	Through August 6, 2013	After August 6, 2013
Member .....	\$1,895	\$2,095
Nonmember .....	2,144	2,344
Government/Health Authority Member .....	700	700
Government/Health Authority Nonmember* .....	800	800
Academic Member .....	700	700
Academic Nonmember* .....	800	800
Student Member .....	280	280
Student Nonmember* .....	310	310

\* Applicable Nonmember rates.

Please visit PDA's Web site at <http://www.pda.org/pdafda2013> 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 your registration information along with your payment 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 at <http://www.pda.org/pdafda2013>.

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:** Please be advised that 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.
- Regulatory Process to Approval (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: April 1, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0126]

### Draft Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food (the draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on issues related to food facility registration under a section of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by May 6, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-