

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 statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments regarding this document 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>.

## III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: February 5, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**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/Xavier University PharmaLink Conference—Quality in a Global Supply Chain

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

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled “FDA/Xavier University PharmaLink Conference.” The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, and includes presentations from key FDA officials, global regulators, and industry experts. Each presentation challenges the status quo and conventional wisdom of our industry to create synergies focused on finding solutions which make a difference. Every discussion, exploration, and solution is framed by the goal of delivering increased patient health and safety through topics such as a working session with the Office of the Commissioner on the implementation of the FDA Safety and Innovation Act, Business Impact of Outsourcing, Supplier Management Models that Work, Implementing Quality by Design (QbD) Successfully—like other industries, lunch with global regulators (FDA, Medicines and Healthcare

products Regulatory Agency (MHRA), Fimea, and Swissmedic), and many more. The experience level of our audience has fostered engaged dialog that has led to innovative initiatives.

**DATES:** The public conference will be held on March 12, 2013, from 8:30 a.m. to 5 p.m.; March 13, 2013, from 8:30 a.m. to 5 p.m.; and March 14, 2013, from 8:30 a.m. to 12:45 p.m.

**ADDRESSES:** The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

#### FOR FURTHER INFORMATION CONTACT:

*For information regarding this notice:* Steven Eastham, Office of Regulatory Affairs, Food and Drug Administration, Cincinnati South Office, 36 East 7th Street, suite 1910, Cincinnati, OH 45202, 513-246-4134, email: [steven.eastham@fda.hhs.gov](mailto:steven.eastham@fda.hhs.gov).

*For information regarding the conference and registration:* Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, email: [phillipsm4@xavier.edu](mailto:phillipsm4@xavier.edu).

#### SUPPLEMENTARY INFORMATION:

**Registration:** There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2½ days of the conference. Advanced registration rate ends February 18, 2013. Standard registration rates begin on February 19, 2013. There will also be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES <sup>1</sup>

| Attendee type                   | Fee Jan. 23–Feb. 18 | Fee after Feb. 18 |
|---------------------------------|---------------------|-------------------|
| Industry                        | \$1,295             | \$1,495           |
| Small Business (<100 employees) | 900                 | 1,000             |
| Consultants                     | 600                 | 700               |
| Startup Manufacturer            | 250                 | 300               |
| Academic                        | 250                 | 300               |
| Media                           | Free                | Free              |
| Government                      | Free                | Free              |

<sup>1</sup> The fourth registration from the same company is free—all four attendees must register at the same time.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the “Registration” link on the conference Web site at <http://www.XavierPharmaLink.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Susan Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35

West 5th Street, Cincinnati, OH 45202, 513-421-9100. To make reservations online, please visit the “Venue & Logistics” link at <http://www.XavierPharmaLink.com>. The hotel is expected to sell out during this timeframe, so early reservation in the conference room block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see **FOR FURTHER INFORMATION**

**CONTACT)** at least 7 days in advance of the conference.

The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- Beyond our Borders—Maximizing the Impact of FDA's Global Interactions
- MHRA, Fimea, and Swissmedic—Driving Safety and Innovation
- Food and Drug Administration Safety and Innovation Act—Be Part of the Solution, and How do we Measure the Effectiveness of the Resulting Change
- Track and Trace in a Global Market
- How do we Gain Greater Supply Chain Visibility?
- Supplier Management Models that Work
- Implementing QbD like Other Industries—Proven Success
- How to Avoid Drug Shortages in your Company
- Pfizer Business Model: Quantitating Culture
- Outsourcing: Business Impact
- FDA, MHRA, and Fimea Inspection Trends and Expectations

The conference includes:

- Lunch with the Regulators—Facilitated, Interactive Session
- Networking by Topic
- Case Studies
- Small Group Discussions
- Innovation Session Engaging the Audience
- Keynote Dinner at the Cincinnati Art Museum with Chairman, CEO, and President of Eli Lilly and Chairman of the Board of PhRMA—John Lechleiter

The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the ongoing health and safety of our patients. These challenges include designing products with the patient in mind, building quality into the product from the onset, selecting the right suppliers, and considering total product life-cycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing our jobs right the first time.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve

objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) (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 conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 6, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities; Proposed Collection, Comment Request

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Information Collection Request Title:* Corps Community Day Event Form—NEW

*Abstract:* Corps Community Day was created in 2011 and celebrates the National Health Service Corps (NHSC) every October during National Primary Care Week. The NHSC is a program administered by the Bureau of Clinician Recruitment and Service (BCRS) within HRSA. The goals of Corps Community Day encompass the following: increase awareness of the NHSC to potential applicants and the greater primary health community; create a sense of community and connectedness among NHSC program participants, alumni, partners, and staff; and underscore the NHSC's role in bringing primary health care services to the nation's neediest communities. Current program participants, alumni, NHSC Ambassadors, sites, primary care organizations, and professional associations plan events and report the details of their events to BCRS so that they can be added to the state-by-state map of events. In order to avoid duplication of effort, eliminate confusion regarding allowable event dates, avoid data entry errors, and implement a brief post-event satisfaction survey, BCRS would like to implement a standard form that event planners will use to report to BCRS. The fillable form will be available online and will have less than 20 fields for event planners to populate to submit for inclusion on the map. There will also be approximately five fields to populate following the event to measure satisfaction. Both the pre-event and post-event data fields will be held in one form.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows: