



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Food and Drug Administration/Xavier University PharmaLink Conference--Leadership 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 co-sponsorship with Xavier University, is announcing a public conference entitled “FDA/Xavier University PharmaLink Conference: Leadership in a Global Supply Chain.” 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 and industry experts.

DATES: The public conference will be held on March 15, 2017, from 8:30 a.m. to 5 p.m.; March 16, 2017, from 8:30 a.m. to 5 p.m.; and March 17, 2017, from 8:30 a.m. to 12:20 p.m. The conference is preceded by a Welcome Reception on March 14, 2017, from 5 p.m. to 7 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3483.

FOR FURTHER INFORMATION CONTACT: For information regarding this notice: Nicholas Paulin, Food and Drug Administration, Cincinnati South Office, 36 East 7th St., Cincinnati, OH 45202, 513-246-4134, email: [nicholas.paulin@fda.hhs.gov](mailto:nicholas.paulin@fda.hhs.gov).

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207-5471, 513-745-3073, email: phillipsm4@xavier.edu.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the on-going health and safety of patients. These challenges include designing products with the patient in mind, building quality into the product from the starting point, selecting the right suppliers, and considering total product lifecycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing the job 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 (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.

The conference includes the following:

- Welcome Reception at the Hilton Netherland Plaza.

- Lunch Networking by Topic.
- The Solution “Xchange”.
- Case Studies and Small Group Discussions.
- Action Plans.

## II. Topics for Discussion at the Public Conference

The public conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- FDA Metrics Program--Path Forward to Reduce Risks Within FDA and Across Industry.
- Predictive Capabilities Through a Living Metrics Model.
- How Big Data and Artificial Intelligence Can Enhance Your Proactive Risk Monitoring Programs.
- Connecting Culture to Performance.
- Data Integrity--Detection and Successful Practices.
- Building a Bridge Across Generations.
- Good Supply Practices (GSPs)--Paradigm Shifting Solutions.
- How to Develop and Execute a Robust Risk-Based Due Diligence Plan.
- Maximizing Post-Merger Success.
- Your Company Bought a New Business--Now What?
- Supply Chains in China--Strategies for Regulatory Success.
- Top 3 Challenges for Successful Serialization Implementation Across Your Supply Chain.

- Strategic Direction of the Food & Drug Administration, Center for Drug Evaluation and Research (CDER), Office of Manufacturing Quality.
- Office of Regulatory Affairs Key Initiatives.
- FDA Investigator Case Study Insights.

### III. Registration for the Public Conference

Registration: To register online for the public conference, please visit the “Registration” link on the conference Web site at <http://www.XavierPharmaLink.com>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. FDA has verified the Web site address in this document, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

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: Marla Phillips, 3800 Victory Pkwy., Cincinnati, OH 45207-5471. An email will be sent confirming your registration.

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.

There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2.5 days of the conference, including the Welcome Reception that precedes the conference. There will be onsite registration if space is available. The cost of registration is as follows:

Table 1.--Registration Fees<sup>1</sup>

Attendee Type	Standard Rate
Industry	\$1,895
Small Business (<100 employees)	\$1,295
Start-up Manufacturer	\$300
Academic	\$300
Media	Free

Government	Free
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<sup>1</sup>The fourth registration from the same company is free. Payment for the three paying registrants must be made prior to registering the fourth person free.

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

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th St., 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.

Dated: February 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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