FOR FURTHER INFORMATION CONTACT: Astrid Lopez-Goldberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5368, Silver Spring, MD 20993–0002, 301–796–3485, *astrid.lopezgoldberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2012–16475, appearing on page 40069 in the **Federal Register** of Friday, July 06, 2012, the following correction is made:

1. On page 40070, in the first column, in the last paragraph, the Web link ''*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm*'' is corrected to read ''*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#narcotics*''.

Dated: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17089 Filed 7–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration/Xavier University Global Outsourcing Conference

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 Global Outsourcing Conference.'' This public conference for the pharmaceutical industry is in direct alignment with the ''FDA Strategic Priorities 2011–2015,'' and includes presentations from key FDA officials, global regulators, and industry experts. This conference drives collaboration on the topic of global outsourcing compliance by bringing pharmaceutical/biotechnology companies and contract partners to the same event to address the issues that reside on both sides of the contract. Expert presentations address the ''how to'' aspects of improving outsourced product quality through topics such as FDA International Initiatives, FDA Inspection Trends, Supply Chain Development, Quality Agreements, Supplier Qualification, and many more. The experience level of our audience has fostered engaged dialogue that has led to innovative initiatives.

Dates and Times: The public conference will be held on September 24, 2012, from 8:30 a.m. to 5 p.m.; September 25, 2012, from 8:30 a.m. to 5:30 p.m.; and September 26, 2012, from 8:30 a.m. to 12:45 p.m.

Location: 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.

Contact Persons:

For information regarding this notice: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East Seventh Street, Cincinnati, OH 45202, 513–246–4134, email: *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.*

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 2 ½ days of the conference. Early registration ends August 5, 2012. Standard registration ends September 2, 2012. Late registration occurs September 3 to September 23, 2012. There will also be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee	Fee on or before August 5th	Fee August 6th–September 2nd	Fee September 3rd–September 23rd
Industry	$995	$1,295	$1,495
Small Business (<100 employees)	800	900	1,000
Consultants	500	600	700
Startup Manufacturers/Academic	200	250	300
Media/Government	Free	Free	Free

[1] The fourth registration from the same company is free.

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 ''Register Now'' link on the conference Web site at *http://www.XavierGOC.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: Sue Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West Fifth St., Cincinnati, OH 45202, 513–421–9100. To make reservations online, please visit the ''Venue & Logistics'' link at *http://www.XavierGOC.com* to make reservations. 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 *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: 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 provide those engaged in FDA-regulated outsourcing with information on the following topics:

- FDA International Initiatives
- European Union Regulator Perspective

- United States Pharmacopeia Chapter Development Impact
- Total Cost of Quality
- FDA New Inspectional Approach and Trends
- Supplier Selection and Due Diligence
- How to Operate in Different Regions of the World
- Establishing a Meaningful Supplier Qualification Program
- Supply Chain Development
- Finished Product Distribution Channel
- Enterprise Resource Planning
- Self Inspections & Corporate Audits
- Quality Agreements
- Business Process Management
- Global Standards Association Near Term Solutions

The conference includes:

- Deep Dive Lunch Sessions
- Live Polling Used by Speakers
- Case Studies
- Small Group Discussions
- Networking Lunch by Topic

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 (Pub. L. 105–115), 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: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17077 Filed 7–12–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0622]

Regulatory Science Considerations for Medical Countermeasure Radiation Biodosimetry Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following public meeting entitled ''Regulatory Science Considerations for Medical Countermeasure (MCM) Radiation Biodosimetry Devices.'' The purpose of the public meeting is to obtain input from academia, Government, industry, and other stakeholders on the clinical application and scientific and technological challenges for performance validation of radiation biodosimetry devices.

Date and Time: The public meeting will be held on September 27 and 28, 2012, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* The public meeting will also be webcast.

Contact: Jennifer S. Dickey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4254, Silver Spring, MD 20993–0002, 301–796–5028, Fax: 301–847–8512, email: *Jennifer.Dickey@fda.hhs.gov.*

Registration: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this public meeting must register online by 4 p.m., September 13, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public meeting will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, email: Susan.Monahan@fda.hhs.gov at least 7 days in advance of the meeting.

To register for the public meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see previous paragraph). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Persons interested in viewing the webcast must register online by 4 p.m., September 13, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 20, 2012. If you have never attended a Connect Pro meeting before, test your connection at: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

Requests for Oral Presentations: This public meeting includes public comment sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comment. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin, and will select and notify participants by September 18, 2012. All requests to make oral presentations must be received by the close of registration on September 13, 2012 by 4 p.m. If selected for presentation, any presentation materials must be emailed to Jennifer Dickey (see *Contact*) no later than September 24, 2012. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Comments: FDA is holding this public meeting to obtain information on the clinical application and scientific and technological challenges for performance validation of radiation biodosimetry devices. In order to permit