Dated: January 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01473 Filed 1–25–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Request for Nominations on the National Mammography Quality Assurance Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) for the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on the NMQAAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by *February 25, 2016,* (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by February 25, 2016.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5215, Silver Spring, MD 20993. 301–796–5960, FAX: 301–847–8505, email: *margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency request nominations for nonvoting industry representatives to the following committee:

I. National Mammography Quality Assurance Advisory Committee

The Committee shall advise the Food and Drug Administration on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the mammography manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Food and Drug Administration/Xavier University PharmaLink Conference: Increasing Product Confidence

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: Increasing Product Confidence''. The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, featuring presentations from key FDA officials, global regulators, and industry experts. Each presentation challenges the status quo and conventional wisdom, to create synergies focused on finding solutions which make a difference. The experience level of the audience has fostered engaged dialogue, which has led to innovative initiatives.

DATES: The public conference will be held on March 16, 2016, from 8:30 a.m. to 5 p.m.; March 17, 2016, from 8:30 a.m. to 5p.m.; and March 18, 2016, from 8:30 a.m. to 12:20 p.m.

ADDRESSES: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207; 513–745–3016.

FOR FURTHER INFORMATION CONTACT: *For information regarding this document:* Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East 7th St., Cincinnati, OH 45202; 513–246–4134, *steven.eastham@fda.hhs.gov.*

For information regarding the conference and registration: Mason Rick, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207–5471; 513–745–3016, *rickm@xavier.edu.*

SUPPLEMENTARY INFORMATION:

I. Background

The most pressing challenges of the global pharmaceutical industry require solutions, which are inspired by collaboration, to ensure the ongoing health and safety of 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 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.

II. Meeting Information

A. Registration

There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts and lunches for the 2.5 days of the conference. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee type	Standard rate
Industry	$1,895
Small Business (<100 employees)	1,295
Supplier	600
Start-up Manufacturer	300
Academic	300
Media	Free
Government	Free

[1] 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 number, email address, and payment information to: Xavier University, Attention: Mason Rick, 3800 Victory Pkwy., Cincinnati, OH 45207–5471. 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 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.

If you need special accommodations due to a disability, please contact Mason Rick (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the conference.

B. Purpose and Scope of Meeting

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:

- Office of Compliance Update
- Data Integrity
- Medicines and Healthcare products Regulatory Agency (MHRA) Update: Strategic Priorities and Initiatives
- Operating in India and Southeast Asia
- Serialization
- Integrity of Supply
- Office of Pharmaceutical Quality Update
- How to Measure Quality Culture
- Pharmaceutical Metrics and the Value Proposition
- Office of Regulatory Affairs Update
- The 21st Century Cures Act: Goals and Impact
- International Conference on Harmonisation Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
- Barriers to Quality and Supply Chain Excellence
- Proactive and Systematic Quality Implementation: Case Studies across functional areas
- FDA and MHRA Investigator Insights

The conference includes:

- Networking by topic
- Case Studies
- Small Group Discussions
- Action Plans
- Keynote dinner at Paul Brown Stadium (Home of the Cincinnati Bengals)

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.

Dated: January 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463, codified at 5 U.S.C.