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.Xavier PharmaLink.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.

[FR Doc. 2016–01486 Filed 1–25–16; 8:45 am]

BILLING CODE 4164–01–P

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.

App.), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders in Newborns and Children

Dates and Times: February 11, 2016, 8:30 a.m. to 5:00 p.m., February 12, 2016, 8:30 a.m. to 3:00 p.m.

Place: Webinar and In-Person, National Institutes of Health, 45 Center Drive Room, Bethesda, MD 20892.

Status: The meeting will be open to the public with attendance limited to space availability. Participants also have the option of viewing the meeting via webinar. Whether attending in-person or via webinar, all participants must register for the meeting. The registration link will be made available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/.* The registration deadline is Friday, February 5, 2016, 11:59 p.m. Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act, Title XI, § 1111 (42 U.S.C. 300b–10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113–240), was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/heritable disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover evidence-informed care and screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) A panel discussion on Long Term Follow-up activities regarding newborns and children identified with a condition via newborn screening. Presentations may include perspectives from state public health experts, researchers, and providers; (2) updates from workgroups focused on cost analysis in newborn screening, newborn screening timeliness, and pilot studies for future nominated conditions; and (3) a discussion on proposed priorities and action items from the three subcommittees (Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training) to develop a plan for 2016. There are no votes that involve proposed additions of a condition to the RUSP scheduled for this meeting.

Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be available on the Committee's Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Registration information will be on the Committee Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.* The registration deadline for public comments is Friday, February 5, 2016, 11:59 p.m. Eastern Time. Written comments must be received by the deadline of January 29, 2016, 11:59 p.m. Eastern Time in order to be included in the February meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.,* parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Alaina Harris, Maternal and Child Health Bureau, Health Resources and Services Administration; email: *aharris@hrsa.gov.*

Contact Person: Anyone interested in obtaining other relevant information should contact Alaina Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W66, 5600 Fishers Lane, Rockville, Maryland 20857; email: *aharris@hrsa.gov.*

More information on the Advisory Committee is available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–01432 Filed 1–25–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the ≤discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Telephone Review SEP.

Date: February 17, 2016.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, Niddk, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; A Community Research Resource of Microbiome-Derived Factors Modulating Host Physiology in Obesity, Digestive and Liver Diseases and Nutrition (R24).

Date: February 29, 2016.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).