



4164-04-P

REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

[BAC 416404]

Annual Public Meeting; Reagan-Udall Foundation for the Food and Drug Administration

ACTION: Notice of annual meeting.

SUMMARY: The Reagan-Udall Foundation for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Administration Amendments Act of 2007, is announcing its annual public meeting. The purpose of this meeting is to provide an opportunity for the Foundation to engage with its stakeholders and receive public input on its efforts. The meeting will include an organizational update, project updates, panel discussion, and open Q & A.

DATES: The public meeting will be held on May 15, 2015, from 10 a.m. until 12 noon.

Registration to attend the meeting and requests for oral presentation must be received by May 8, 2015. See the SUPPLEMENTARY INFORMATION section for information on how to register for the meeting.

ADDRESSES: The public meeting will be held The Pew Charitable Trusts Conference Center, 901 E St. NW., Washington, DC 20004. Entrance for the meeting is located on 9th St. NW., between F St. NW. and E St. NW.

FOR FURTHER INFORMATION CONTACT: Jane Reese-Coulbourne, Reagan-Udall Foundation for the FDA, 202-828-1205, Meetings@ReaganUdall.org.

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA (the Foundation) is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research projects to advance regulatory science.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how Reagan-Udall Foundation projects can help the Agency to fulfill its mission.

The Foundation's programmatic efforts are designed to improve the existing scientific tools (methods) used to evaluate products as well as foster the development of innovative tools and approaches. This is exemplified in the Foundation's projects including: The Innovation in Medical Evidence Development and Surveillance Program, which develops and evaluates methods for using observational electronic health care data for postmarket evidence generation, including postmarket safety surveillance; the PredicTox Project, which applies systems biology to develop mechanistic models to predict adverse events; and the Critical Path to Tuberculosis Drug Regimens Project, which looks at novel approaches to development and review of tuberculosis combination therapies. Additionally, the Foundation is establishing regulatory

science fellowships as part of its broader education efforts aimed at building capacity in regulatory science.

II. Meeting Attendance and Participation

A. Registration

If you wish to attend the meeting, visit: <http://goo.gl/GX6ysw>. Please register for the meeting by May 8, 2015. Seating may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the meeting will be based on space availability.

B. Requests for Oral Comments

Interested persons may present comments at the public meeting. Comments will be scheduled to begin approximate at 11:40 a.m. Time allotted for comments may be limited to 3 minutes, dependent on number of requests received. Those desiring to make oral comments should notify Jane Reese-Coulbourne (see FOR FURTHER INFORMATION CONTACT) by May 8, 2015. Please include a brief statement of the general nature of the comments they wish to present along with your name, address, telephone number, and email.

The agenda for the public meeting will be posted on the event registration page: <http://goo.gl/GX6ysw> and the Reagan-Udall Web site: <http://goo.gl/aSVymH>.

C. Written Comments

Interested persons may submit either electronic or written comments to the Foundation at any time to Comments@ReaganUdall.org, or by mail to the Reagan-Udall Foundation for the FDA, 1025 Connecticut Ave. NW., Suite 1000, Washington, DC 20036. Please include your name, address, telephone number, and email when making comments.

III. Post-Meeting Materials

The Foundation plans to make meeting materials and meeting recording available to the public after the meeting. Once available, these materials will be posted at <http://goo.gl/aSVymH>.

Dated: April 15, 2015.

Jane Reese-Coulbourne,

Executive Director,

Reagan-Udall Foundation for the FDA.

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