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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

First Annual Neonatal Scientific Workshop--Roadmap for Applying Regulatory Science to Neonates; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public scientific workshop to discuss the roadmap for applying regulatory science to neonates. This public scientific workshop is being co-sponsored with the FDA, the Critical Path Institute (C-Path) and the Burroughs Welcome Fund (BWF).

The purpose of the public scientific workshop is to initiate constructive discussion among regulators, researchers, health care providers, representatives from the pharmaceutical industry and health care organizations, and the general public to determine whether there is sufficient interest on the part of stakeholders to develop a neonatal consortium and to discuss potential working groups dedicated to the regulatory science required to develop neonatal therapeutics.

DATES: The public scientific workshop will be held on October 28 and 29, 2014, from 8 a.m. to 5 p.m. Section II provides attendance and registration information.

ADDRESSES: The public scientific workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public scientific workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be

performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Indira Hills, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, rm. 4508, Silver Spring, MD 20993, 301-796-9686, FAX: 301-796-9907, indira.hills@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

C-Path and BWF, in cooperation with FDA and various stakeholders, including industry, academia, professional organizations, patient advocacy groups, and other government Agencies, are proposing to establish the Neonatal Consortium in order to leverage resources and expertise toward mutually beneficial goals and in the interest of public health. Some of the potential priorities of the Neonatal Consortium to be discussed at the public scientific workshop would be the following:

1. Developing and qualifying biomarkers, clinical outcome assessments, and other drug development tools. Valid and reliable endpoints are presently lacking in neonatal clinical trials.
2. Developing physiologically-based pharmacokinetic modeling and simulation to predict on and off target responses to drugs.
3. Optimizing clinical trial designs for the neonatal population. One aspect of clinical trial design in neonates is the need for long-term studies to properly evaluate the effects of an intervention. There is also interest in examining bioethical questions related to neonatal care and their solutions.

4. Maximizing the use of registry data. Such registries may be useful in long-term studies.
5. Developing Clinical Data Interchange Standards Consortium data standards for registry data, electronic health record information, and clinical trial data.
6. Building a neonatal database in which standardized data pooled from industry and academic neonatal trials could reside. Such a database would be an invaluable resource for the neonatal community.

II. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to participate in the public scientific workshop (in person or via web) must register on or before October 20, 2014, by visiting http://www.cvent.com/d/34qr03 and contacting Indira Hills (see FOR FURTHER INFORMATION CONTACT) or Kerrie Bennymadho, Project Coordinator, Critical Path Institute, 520-382-1377, Cell: 760-636-3046, kbennymadho@c-path.org regarding registration. Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the public scientific workshop will be based on space availability. The registration deadline is October 20, 2014.

FDA will provide additional background information at the time the Federal Register notice is published and an agenda approximately 2 weeks before the public scientific workshop at FDA Meeting Information page, which is available online at http://www.fda.gov/Drugs/NewsEvents/ucm410863.htm.

If you need special accommodations because of disability, please contact Indira Hills (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the public scientific workshop.

A live Webcast of this public scientific workshop will be viewable at Adobe Connect Link: https://collaboration.fda.gov/nsw2014/ on the day of the public scientific workshop. A video record of the public scientific workshop will be available at the same Web address for 1 year.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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