FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, at 301–796–5966. *Annmarie.williams@fda.hhs.gov* at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 16, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–22444 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

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.

[FR Doc. 2014–22460 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Direct Impact Corona Ionization Mass Spectrometry

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the Food and Drug Administration, an agency within the Department of Health and Human Services, through the National Institutes of Health Office of Technology Transfer is contemplating the grant of an exclusive worldwide license to practice the inventions embodied in HHS Ref. No. E–258–2011/0, ''Direct Impact Corona Ionization (DICI) Mass Spectrometry;'' U.S. Patent 8,704,169, to Vivione Biosciences, Inc., a corporation incorporated under the laws of the State of Arkansas, having a principle place of business at 515 W. Matthews Ave., Jonesboro, AR 72401.

The United States of America is the assignee of the patent rights pertaining to this invention.

The exclusivity period of the contemplated license may be granted for no more than seven (7) years, may be territorially limited to the United States and may be limited to a field of use directed to direct impact corona ionization mass spectrometry pattern recognition devices and systems for detection of small molecules and microbiological agents.

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before October 22, 2014 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq, CLP, Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5019; Facsimile: (301) 402–0220; Email: *shmilovm@mail.nih.gov.* A signed confidential disclosure agreement may be required to receive copies of the patent application assuming it has not already been published under the publication rules of either the U.S. Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: E–258–2011/0 (U.S. Patent 8,704,169)—The invention relates to the uses of an AccuTOF DART (time-of-flight mass spectrometer coupled to direct analysis in real time) mass spectrometer for qualitatively analyzing samples (originally designed for microbes) based on the serendipitous discovery that glowing direct impact corona ionization greatly enhances sensitivity of identification. This direct impact corona ionization occurred while repositioning the stainless steel pin too close to the grid of the ion source gun. Examination revealed that not only did the peak intensity increase by 490 fold but the spectral information was well beyond anything seen before with only the normal ionization mode on the same instrument. Initially, pyrolysis was considered necessary for vaporizing low volatility components of microbiological analytes, a prerequisite for ionizing and introducing samples into the mass spectrometer. However, pyrolysis introduced particles from burned electrical wiring insulation because of the high current necessary. As an alternative, the inventors replaced the pyrolysis device with a power generator used for direct corona ionizing microbiological analytes in a controlled fashion. Furthermore, a small custom-made glass cylinder with two juxtaposing holes on each side was set up within the sample introduction chamber to exclude oxygen thus preventing oxidation of microbiological analytes. Additionally, the insulation provided by this cylinder kept out ambient moisture thus ensuring proton transfer from water molecules would not contribute to irreproducible ionization of the analyte.

The prospective exclusive license will be royalty-bearing and comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, the National Institutes of Health Office of Technology Transfer receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 18, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–22454 Filed 9–19–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, Clinical and Translational Imaging Applications.

Date: October 15, 2014.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Eileen W Bradley, DSC, Chief, SBIB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Vascular Biology of Diabetes and Atherosclerosis.

Date: October 15, 2014.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anshumali Chaudhari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124,