Dated: March 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08618 Filed 4–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Joint Workshop on Drug Transporters in Absorption, Distribution, Metabolism, and Excretion: From the Bench to the Bedside

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Drug Transporters in Absorption, Distribution, Metabolism, and Excretion (ADME): From the Bench to the Bedside.'' The public workshop is an American Association of Pharmaceutical Scientists/International Transporter Consortium (AAPS/ITC) Joint Workshop, cosponsored with AAPS, the American Society for Clinical Pharmacology and Therapeutics, and the European Federation for Pharmaceutical Sciences. The goals of this public workshop are to provide an opportunity for scientists in academia, industry, and regulatory agencies to exchange ideas about the cutting edge science in transporters, and to facilitate and enhance translational applications of new development in transporter research in drug development and regulatory review of new therapeutics.

Date and Time: The public workshop will be held on April 20, 2015, from 8:15 a.m. to 7 p.m.; April 21, 2015, from 8 a.m. to 6:30 p.m.; and April 22, 2015, from 8 a.m. to 3:45 p.m.

Location: The public workshop will be held at the Renaissance Baltimore Harborplace Hotel, 202 East Pratt St., Baltimore, MD 21202. The hotel's phone number is 410–547–1200.

Contacts: FDA: Lei Zhang, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 3196, Silver Spring, MD 20993, 301–796–1635, email: *leik.zhang@fda.hhs.gov. AAPS:* For questions related to this event, please contact AAPS at *registration@aaps.org.*

Registration: Workshop information and the registration link are posted at the AAPS meetings and professional development conference site. To register for the workshop, please visit *http://www.aaps.org/Meetings_and_Professional_Development/Conference_Mini_Sites/AAPS_WS_Transporters15/Register/.* The cost of registration is as follows:

AAPS Member	$1,815
Nonmember	2,190
Government	675
Academic	880
Student	110

The registration fee will be waived for 50 FDA employees. If you need special accommodations because of a disability, please contact AAPS at *registration@aaps.org.* Onsite registration on the day of the workshop will be available.

Additional Information About the Workshop: The workshop agenda and additional background materials will be accessible at *http://www.fda.gov/Drugs/NewsEvents/ucm439157.htm* to all registrants.

SUPPLEMENTARY INFORMATION:

I. Background

Transporters serve an important role in the ADME of drugs, and in turn could affect their safety or efficacy. The AAPS/ITC joint transporter workshop in 2015 aims to continue on the success of preceding AAPS workshops on Drug Transporters meetings (2003, 2005, 2007, 2009, 2011, 2013) and ITC transporter workshops (2008 and 2012) to provide an opportunity for scientists in academia, industry, and regulatory agencies to exchange ideas about the cutting-edge science. Key areas of focus will include the following:

- Transporter tools of the future (*e.g.,* organs-on-a-chip, humanized mouse models, and transporter imaging);
- Interplay of drug metabolism and transporters;
- ''State of the art'' sessions on:
  - Emerging transporters,
  - Endogenous biomarkers to assess transporter-mediated drug efficacy and toxicity or to predict drug-drug interactions, and
  - Quantitative transporter proteomics in translational drug metabolism and pharmacokinetics;
- ''Hot Topics'' in the translation of transporter data to the clinic;
- Prospective transporter substrate modeling; and
- Review of comments related to transporters following recent guidances issued from the regulatory agencies, including FDA, European Medicines Agency, and Pharmaceuticals and Medical Devices Agency (Japan).

II. Goals and Objectives

- To provide a forum for open interchange, dissemination, and discussion of cutting edge science in transporters among scientists from academia, industry, and regulatory agencies.
- To develop a mutual understanding on what needs to be done in transporter research and how to translate knowledge obtained from the bench to bedside.
- To facilitate and enhance translational applications of new development in transporter research in drug development and regulatory review of new therapeutics.

Dated: April 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Request for Nomination for Industry Representatives and Participation From Industry Organizations on Public Advisory Committees

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 its public advisory committees for the Center for Drug Evaluation and Research (CDER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CDER's public advisory committees. 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 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 FDA by May 15, 2015, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by May 15, 2015.

ADDRESSES: All statements of interest from interested industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be

sent to Cicely Reese (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at *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 *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Cicely Reese, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *Cicely.Reese@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative to the following advisory committees:

I. CDER Advisory Committees

A. *Advisory Committee for Pharmaceutical Science and Clinical Pharmacology:* Reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases.

B. *Anesthetic and Analgesic Drug Products Advisory Committee (formerly Anesthetic and Life Support Drugs Advisory Committee):* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

C. *Anti-Infective Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

D. *Antiviral Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections. (Terminated February 15, 2015).

E. *Arthritis Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.

F. *Bone, Reproductive, and Urologic Drugs Advisory Committee (formerly Advisory Committee for Reproductive Health Drugs):* Reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, and related specialties.

G. *Cardiovascular and Renal Drugs Advisory Committee:* Reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders.

H. *Dermatologic and Ophthalmic Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

I. *Drug Safety and Risk Management Advisory Committee:* Reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use.

J. *Endocrinologic and Metabolic Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

K. *Gastrointestinal Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases.

L. *Medical Imaging Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

M. *Nonprescription Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

N. *Oncologic Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer.

O. *Peripheral and Central Nervous System Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

P. *Pharmacy Compounding Advisory Committee:* Provides advice on scientific, technical, and medical issues concerning drug compounding.

Q. *Psychopharmacologic Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

R. *Pulmonary-Allergy Drugs Advisory Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

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.

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: April 9, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–08620 Filed 4–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1083]

Innovations in Medical Evidence Development and Surveillance-Methods Research Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of Center for Drug Evaluation and Research (CDER). The goal of the CDER is to support the development of appropriate methodologies to conduct medical product safety surveillance in large electronic databases. Innovations in Medical Evidence Development and Surveillance (IMEDS)-Methods is a program within the Reagan-Udall Foundation that supports FDA's scientific mission of serving public health needs by initiating and facilitating research into the methods of safety evaluation in large databases.

DATES: 1. The application due date is June 15, 2015.

2. The anticipated start date is July 15, 2015.

3. The opening date is April 13, 2015.

4. The expiration date is June 16, 2015.

ADDRESSES: Submit the electronic application to: *http://www.grants.gov*. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Patrick Archdeacon, Food and Drug Administration, Bldg. 51 Rm.6314, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3952; or Vieda Hubbard, Division of Acquisition Support and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240–402–7588.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at: *http://www.grants.gov/*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–15–010 93.103

A. Background

Section 905 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) mandates FDA to develop an enhanced ability to monitor the safety of drugs after these products reach the market. In response to this mandate, FDA launched its Sentinel Initiative, a long-term program designed to build and implement an electronic system for monitoring the safety of medical products in the post market setting. FDA has already created significant infrastructure on which to operate such a system: Through its Mini-Sentinel pilot, a distributed database with access to more than 150 million patient records has been created (the Sentinel Distributed Database). In order to optimally leverage these data, however, new analytic methodologies will be required. IMEDS-Methods is a program within the Reagan-Udall Foundation that supports FDA's scientific mission of serving public health needs by initiating and facilitating research into the methods of safety evaluation in large databases. IMEDS-Methods aims to improve the tools for conducting post-marketing safety surveillance using automated healthcare data and to foster their adoption.

B. Research Objectives

IMEDS plans to conduct methods research in five core areas: (1) Addressing bias in estimates from observational studies; (2) better understanding uses and limitations of the data; (3) applying lessons learned from earlier IMEDS projects to FDA surveillance activities; (4) expanding the surveillance question to continuous risk/benefit assessment; and (5) continuing to support qualified investigators in industry, government, and academic settings by providing access to de-identified electronic healthcare data and computing resources through the IMEDS Research Laboratory.

C. Eligibility Information

Eligibility is limited to the Reagan-Udall Foundation. The Reagan-Udall Foundation has established the IMEDS-Methods program, which is uniquely positioned to develop the new methodologies required for FDA to conduct effective active post market safety surveillance of medical products using large electronic health care data. The IMEDS organization has developed a network of statisticians, epidemiologists, data scientists, and clinicians who have experience operating in both the IMEDS research laboratory and also familiarity with the Sentinel Distributed Database. In addition, through the Reagan-Udall Foundation public-private partnership, the IMEDS-Methods program has a unique ability to convene FDA, patients, academics, government, and industry so that the findings and tools developed through its research agenda will be promulgated and adopted.

II. Award Information/Funds Available

A. Award Amount

FDA/CDER intends to fund up to $1,000,000 in fiscal year 2015 in support of this program project. It is anticipated that only one award will be made, not to exceed $1,000,000 (direct plus indirect) for total costs.

B. Length of Support

There is a one year period of performance beginning on June 15, 2015 or the date of award.

III. Electronic Application, Registration, and Submission

Only one electronic application will be accepted. To submit an electronic application in response to this FOA, the applicant should first review the full announcement located at *http://www.grants.gov/*. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

For the electronically submitted application, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password