

Dated: March 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]

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/Registrar/. The cost of registration is as follows:

www.aaps.org/Meetings_and_Professional_Development/Conference_Mini_Sites/AAPS_WS_Transporters15/Registrar/. 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.

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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