

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2012-N-0471]

Agency Information Collection Activities: Proposed Collection; Comment Request; User Fee Cover Sheet; Form FDA 3397**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Form FDA 3397, User Fee Cover Sheet, that must be submitted along with certain drug and biologic product applications and supplements.

DATES: Submit either electronic or written comments on the collection of information by June 15, 2015.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

User Fee Cover Sheet; Form FDA 3397 (OMB Control Number 0910-0297)—Extension

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications (BLAs) and supplements to

those applications. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications (NDAs), BLAs, or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA’s Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs, BLAs, and/or, supplemental applications to those applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA’s database system for fiscal year (FY) 2014, there are an estimated 290 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105–115). The total number of annual responses is based on the number of submissions received by FDA in FY 2014. CDER received 3,005 annual responses that include the following submissions: 128 NDAs; 7 BLAs; 1,586 manufacturing supplements; 1,081 labeling supplements; and 203 efficacy supplements. CBER received 705 annual responses that include the following submissions: 11 BLAs; 611 manufacturing supplements; 64 labeling supplements; and 19 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3397	290	12.79	3,710	0.5 (30 min.)	1,855

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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

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