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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

American Association of Pharmaceutical Scientists/American College of Clinical Pharmacology/American Society for Clinical Pharmacology and Therapeutics/Food and Drug Administration Cosponsored Workshop on "Evaluating and Modernizing our Approaches for Food-Effect Assessment"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Evaluating and Modernizing our Approaches for Food-Effect Assessment," cosponsored with the American Association of Pharmaceutical Scientists (AAPS), the American College of Clinical Pharmacology (ACCP), and the American Society for Clinical Pharmacology and Therapeutics (ASCPT). The goals of this public workshop are to facilitate discussion on current scientific approaches on assessing the effect of food on the pharmacokinetics and pharmacodynamics of drugs and to initiate constructive discussion and information sharing among relevant stakeholders on the influence of food-effects on the pharmacokinetic properties of therapeutics in order to optimize dose and dosing regimens.

Date and Time: The workshop will be held on February 2, 2015, from 8 a.m. to 5 p.m., February 3, 2015, from 8 a.m. to 5 p.m., and February 4, 2015, from 8 a.m. to 12:15 p.m.

Location: The workshop will be held at the Renaissance Baltimore Harborplace Hotel, 202 East Pratt St., Baltimore, MD 21202.

Contacts: FDA: Padmaja Mummaneni, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 2164, Silver Spring, MD 20993, 301-796-2027, padmaja.mummaneni@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_Food/Register/. The cost of registration is as follows:

Member	$1,690
Nonmember	$2,070
Government	$650
Student	$100

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

Additional Information about the Workshop: The workshop agenda and additional background materials will be accessible at http://www.fda.gov/Drugs/NewsEvents/ucm428914.htm to all registrants.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's guidance for industry entitled "Food-Effect Bioavailability and Fed Bioequivalence Studies" (Food-Effect Guidance) is an important tool in the development of new oral therapeutics. Studies are conducted according to the principles described for every new

drug that is intended to be administered by the oral route. The Food-Effect Guidance was first published in 2002. Since that time, numerous studies have been reported in the literature in an effort to address a number of different aspects related to assessing the effect of food on the pharmacokinetics and pharmacodynamics of drugs. Predominantly, these studies have addressed the impact of food composition on the physiology of drug absorption. In vitro studies have aimed at elucidating the individual mechanism(s) of drug absorption, and a number of in vivo studies have addressed the effects of different meal compositions on the pharmacokinetics of drugs.

FDA has undertaken an effort to revise the 2002 Food-Effect Guidance and is seeking feedback from academia, industry, and other stakeholders on several issues. FDA, AAPS, ACCP, and ASCPT agreed to cosponsor this workshop to provide a forum for input on the best available science on this topic from academia, industry, other stakeholders, and regulators.

II. Goals and Objectives

- To provide a forum for open discussion between industry, academia, other stakeholders, and FDA around proposed changes to the Food-Effect Guidance.
- To seek feedback from industry, academia, and other stakeholders on FDA's proposals and to seek any additional input that will benefit decision making on a guidance revision on the topic.

Dated: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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