the United States. It is not controlled internationally under the Convention on Psychotropic Substances or the Single Convention on Narcotic Drugs. The WHO Expert Committee on Drug Dependence reviewed ketamine at its 34th, 35th, and 36th meetings. Ketamine is controlled in schedule III of the CSA in the United States, and additional controls may be necessary to fulfill U.S. obligations if ketamine is controlled under Schedule I of the Psychotropic Convention. FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the Psychotropic Convention at the CND meeting in March 2015.

Comments regarding the WHO recommendations for control of AH-7921 under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S. position regarding narcotic substances at the CND meeting.

IV. Submission of Comments and Opportunity for Public Meeting

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

FDA does not presently plan to hold a public meeting. If any person believes that, in addition to written comments, a public meeting would contribute to the development of the U.S. position on the substances to be considered for control under the Psychotropic Convention, a request for a public meeting and the reasons for such a request should be sent to James R. Hunter (see **FOR FURTHER INFORMATION CONTACT**) on or before February 6, 2015.

The short time period for the submission of comments and requests for a public meeting is needed to ensure that HHS may, in a timely fashion, carry out the required action and be responsive to the United Nations.

Dated: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01408 Filed 1–26–15; 8:45 am]

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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.

[FR Doc. 2015–01409 Filed 1–26–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Food and Drug Administration/Xavier University PharmaLink Conference—Leadership in a Global Supply Chain

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University PharmaLink Conference: Leadership in a Global Supply Chain.'' The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA and includes presentations from key FDA officials, global regulators, and industry experts. Each presentation challenges the status quo and conventional wisdom to create synergies focused on finding solutions which make a difference. The experience level of the audience has fostered engaged dialog that has led to innovative initiatives.

Dates and Times: The public conference will be held on March 25, 2015, from 8:30 a.m. to 5 p.m.; March 26, 2015, from 8:30 a.m. to 5 p.m.; and March 27, 2015, from 8:30 a.m. to 12:45 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3020.

Contact Persons: For information regarding this notice: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East 7th Street, Cincinnati, OH 45202, 513–246–4134, email: *steven.eastham@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207–5471, 513–745–3073, email: *phillipsm4@xavier.edu.*

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2½ days of the conference. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee type	Early rate (on or before 1/24/15)	Advanced rate (1/25/15 to 2/24/15)	Standard rate (after 2/24/15)
Industry	$1,295	$1,695	$1,895
Small Business (<100 employees)	995	1,195	1,295
Startup Manufacturer	200	250	300
Academic	200	250	300
Media	Free	Free	Free
Government	Free	Free	Free

[1] The fourth registration from the same company is free—all four attendees must register at the same time.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the ''Registration'' link on the conference Web site at *http://www.XavierPharmaLink.com.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Mason Rick, 3800 Victory Pkwy., Cincinnati, OH 45207–5471. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH 45202, 513–421–9100. To make reservations online, please visit the ''Venue & Logistics'' link at *http://www.XavierPharmaLink.com.* The hotel is expected to sellout during this timeframe, so early reservation in the conference room-block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- Major Changes at FDA Affecting You
- FDA-Driven Initiatives through Food and Drug Administration Safety and Innovation Act Implementation
- Held at the Border? Understand Why
- Toyota Production System—Cultural Requirements
- Barriers to Quality and Supply Chain Excellence
- Establishing Good Supply Practices
- Medicines and Healthcare Products Regulatory Agency Perspective on Global Supply Chain Challenges
- Systematic Approach to Managing Your Global Supply Chain
- Deep Dive Lunch Session—Clinically Relevant Metrics
- Deep Dive Lunch Session—Data Integrity: How To Verify You Are Okay
- Deep Dive Lunch Session—Integrity of Supply Workshop
- Nobel Prize-Based Alignment Optimization