4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Annual Computational Science Symposium; Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the

Pharmaceutical Users Software Exchange (PhUSE), is announcing a public conference entitled

"The FDA/PhUSE Annual Computational Science Symposium." The purpose of the conference

is to help the broader community align and share experiences to advance computational science.

At the conference, which will bring together FDA, industry, and academia, FDA will update

participants on current initiatives, and collaborative project groups will address specific

challenges in accessing and reviewing data to support product development. These project

groups will focus on solutions and practical ways to implement them.

DATES: The public conference will be held on March 18 and 19, 2013, from 9 a.m. to 5:30 p.m.

ADDRESSES: The public conference will be held at the Silver Spring Civic Building at

Veterans Plaza, One Veterans Pl., Silver Spring, MD 20910, 1-240-777-5300.

FOR FURTHER INFORMATION CONTACT:

Chris Decker,

PhUSE FDA Liaison Director,

Pharmaceutical Users Software Exchange (PhUSE),

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Broadstairs CT10 1JT, United Kingdom,

609-514-5105,

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SUPPLEMENTARY INFORMATION:

A description of the project groups and planned activities can be found at

http://www.phuse.eu/css.

I. Registration and Accommodations

A. Registration

To register, please submit the registration form online at https://www.phuse.eu/PhUSE-CSS-2013-Registration.aspx. (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.) Registration fees cover the cost of facilities, materials, and food functions. Seats are limited, and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference.

The costs of registration for different categories of attendee are as follows:

Category	Cost
Industry representatives registering by February 15, 2013	$700
Industry representatives registering after February 15, 2013	$900
Those with government affiliation	$300
Representatives of nonprofit organizations	$300
Those attending for a single day	$650

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to: office@phuse.eu. All registrants will pay a fee with the exception of a limited number of speakers/organizers who will have a complimentary registration.

B. Accommodations

Attendees are responsible for their own accommodations. Attendees making reservations at the DoubleTree by Hilton Silver Spring Hotel are eligible for a reduced conference rate of $199, not including applicable taxes. Those making reservations online should use the following link to receive the special rate:

http://doubletree.hilton.com/en/dt/groups/personalized/D/DCASSDT-PUE-20130316/index.jhtml?WT.mc_id=POG. If you need special accommodations because of disability, please contact Chris Decker (see FOR FURTHER INFORMATION CONTACT) at least 14 days before the meeting.

II. Information for Presenters of Posters and Exhibits

Those wishing to present posters at the conference should submit an abstract online at http://www.phuse.eu/Call_for_NewProjectsCSS.aspx. Suggested poster abstract topics include:

- Data submission standards development, implementation, and best practices;
- user experience and evaluation of current processes and tools and their effects on organizational performance;
- needs and specifications for proposed new tools and processes;
- business processes driving the development of information systems; and
- the effect of processes and tools on problem solving quality, efficiency, and cost.

All abstracts must be received by February 15, 2013, and authors whose posters have been accepted will be notified by February 28, 2013.

The conference will make available an exhibition hall. The exhibitor price for this conference is $3,500. Neither PhUSE nor FDA endorse any commercial software or vendor. Dated: February 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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