

indication of long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 8, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 31, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 1, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on

public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Blood Products Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Blood Products Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the Agency on FDA's regulatory issues.

**DATES:** *Date and Time:* The meeting will be held on February 29, 2012, from 8:30 a.m. to 4 p.m.

**Location:** Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877, (301) 977-8900. For those unable to attend in person, the meeting will also be Web cast. The Blood Products Advisory Committee Web cast will be available at <http://fda.yorkcast.com/webcast/Viewer/?peid=11253ea88a9041e5a91883236f342bfc1d>.

**Contact Person:** Bryan Emery or Pearl Muckelvene, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, (301) 827-1281, or FDA Advisory Committee Information Line, 1-(800) 741-8138 (301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and

call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** On February 29, 2012, the committee will discuss the evaluation of possible new plasma products manufactured following storage at room temperature for up to 24 hours, namely, plasma for transfusion prepared from whole blood held at room temperature for up to 24 hours prior to separation and freezing, or from apheresis plasma held at room temperature for up to 24 hours before freezing. In the afternoon, the committee will hear the following updates: Report from the Health and Human Services Advisory Committee on Blood Safety and Availability and summary of the December 5-6, 2011, meeting; update on HHS activities related to the evaluation of the donor deferral policy for men who have had sex with other men; summary of the November 8-9, 2011, public workshop on hemoglobin standard and maintaining an adequate blood supply; summary of the November 29, 2011, public workshop on data and data needs to advance risk assessment for emerging infectious diseases for blood and blood products; and an update on thrombotic adverse events and immune globulin products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 21, 2012. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 12:45 p.m. on February 29, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 13, 2012. Time allotted for each presentation may be

limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 14, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery or Pearl Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

### Annual Computational Science Symposium; Public 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 working

groups will address specific challenges in accessing and reviewing data to support product development. These working groups will focus on solutions and practical ways to implement them.

**DATES:** *Date and Time:* The public conference will be held on March 19 and 20, 2012, from 9 a.m. to 4:30 p.m.

*Location:* 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.

*Contact:* Chris Decker, U.S. Regional Director, Pharmaceutical Users Software Exchange (PhUSE), 64 High St., BROADSTAIRS CT10 1JT, United Kingdom, (202) 386-6722, e-mail: [office@phuse.eu](mailto:office@phuse.eu).

#### SUPPLEMENTARY INFORMATION:

#### I. Working Groups and Their Areas of Focus

Six working groups will address particular challenges related to the access and review of data to support product development:

- Working Group 1: Data Validation and Quality Assessment,
- Working Group 2: Reducing Risk Within the Inspection Site Selection Process,
- Working Group 3: Challenges of Integrating and Converting Data Across Studies,
- Working Group 4: Standards Implementation Issues With the Clinical Data Interchange Standards Consortium Data Models,
- Working Group 5: Development of Standard Scripts for Analysis and Programming, and
- Working Group 6: "Non-Clinical Road-Map" and Impacts on Implementation.

A description of the planned activities of the working groups can be found at <http://www.phuse.eu/Working-Groups.aspx>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

#### II. Registration and Accommodations

##### A. Registration

To register, please submit the registration form online at <https://www.phuse.eu/PhUSE-Conference-2012-Registration.aspx>. 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:

#### COST OF REGISTRATION

| Category                                                          | Cost  |
|-------------------------------------------------------------------|-------|
| Industry representatives registering by January 15, 2012 .....    | \$750 |
| Industry representatives registering after January 15, 2012 ..... | 950   |
| Those with Government affiliation ....                            | 300   |
| Representatives of nonprofit organizations .....                  | 600   |
| 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](mailto: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 Courtyard by Marriott Silver Spring Downtown Hotel are eligible for a reduced conference rate of \$199, not including applicable taxes. Those making reservations online should use the group code "SPRSPRB" to receive the special rate. If you need special accommodations because of disability, please contact Chris Decker (see *Contact*) at least 7 days before the meeting.

#### III. Posters and Exhibits Information

Posters will be presented and may include demonstrations to provide an interactive experience. Although PhUSE welcomes demonstrations to support and explore the posters that are presented, neither PhUSE nor FDA endorse any commercial software or vendor. The creator of what is judged the best poster will be recognized and offered the opportunity to present the poster at the closing session.

Poster 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.