

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

**Time and Date:** 8:00 a.m.–12:00 p.m., June 11, 2012 (Closed).

**Place:** Crowne Plaza Hotel Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road, Atlanta, Georgia 30346.

**Status:** The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

**Matters To Be Discussed:** The meeting will include the initial review, discussion, and evaluation of applications received in response to “Field Triage of Traumatic Brain Injury (TBI) in Older Adults Taking Anticoagulants or Platelet Inhibitors, FOA CE12-005.”

**Contact Person for More Information:** J. Felix Rogers, Ph.D., M.P.H., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F63, Atlanta, Georgia 30341, Telephone (770) 488-4334.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 15, 2012.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0377]

#### Clinical Study Design and Performance of Hospital Glucose Sensors

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

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following public meeting entitled “Clinical Study Design and Performance of Hospital Glucose Sensors.” The purpose of this public meeting is to discuss clinical study design considerations and performance metrics for innovative glucose sensors intended to be used in hospital point of care settings.

**DATES:** *Date and Time:* The public meeting will be held on June 25, 2012, from 8 a.m. to 5 p.m.

**Location:** The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. The public meeting will also be available to be viewed online via webcast.

**Contact:** Vicki Moyer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5626, Silver Spring, MD 20993, 301-796-6148, FAX: 301-847-8513, email: [vicki.moyer@fda.hhs.gov](mailto:vicki.moyer@fda.hhs.gov).

**Registration:** Registration is free and on a first-come, first-served basis. Persons interested in attending this meeting must register online by 4 p.m., June 15, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the meeting will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993, 301-796-5661, email: [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov), no later than June 15, 2012.

To register for the public meeting, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see *Registration* section of this document). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

**Streaming Web cast of the Public Meeting:** This public meeting will also be Web cast. Persons interested in viewing the Web cast must register online by 4 p.m., June 15, 2012. Early registration is recommended because Web cast connections are limited. Organizations are requested to register

all participants, but to view using one connection per location. Web cast participants will be sent technical system requirements after registration and will be sent connection access information after June 20, 2012. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

**Requests for Oral Presentations:** This public meeting includes a public comment session. During online registration you may indicate if you wish to speak and the proposed title for the public comment session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comment. Following the close of registration, FDA will determine the amount of time allotted to each speaker and will select and notify participants by June 19, 2012. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

**Comments:** FDA is holding this public meeting to obtain information on innovative kinds of hospital glucose sensors. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting electronic or written comments on all aspects of the meeting topics. The deadline for submitting comments related to this public meeting is July 23, 2012.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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>.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the meeting on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this meeting from the posted events list.).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is seeking input from the clinical community, academia, Government, industry, clinical laboratories, and other stakeholders regarding clinical validation studies and performance criteria for hospital glucose sensors. These types of devices are intended to be used at the patient bedside, and are different from currently available glucose sensors in that they are generally indwelling or inserted. Furthermore, they are often designed to collect continuous or near-continuous glucose concentrations for each patient.

These devices have the potential to benefit patient care but to date they are not widely available. This is due, in part, to the challenges in designing and studying these complex devices. One challenge is the study design itself; determining the types of patients to include and what data are needed to adequately validate performance is often difficult given the varied hospital environment and patient populations. Once the study is complete, determining whether or not the results are sufficiently accurate and reliable for the proposed intended use(s) is equally challenging.

The purpose of this public meeting is to share information about the challenges in validating these kinds of hospital glucose sensors and solicit public input and discussion. The feedback may increase communication and collaboration within the stakeholder community, and, ultimately, help overcome some of the current challenges associated with designing clinical studies and generating clinical performance data for these devices.

The public meeting will include two sessions of the following topics: (1) The clinical studies and data needed to

adequately validate the performance of these devices in the intended use population and (2) discussion of metrics that may be used to evaluate results to demonstrate a safe and effective device. Each session will include presentations from physicians, Government, and other experts in the field. Presentations will be followed by panel discussions of session topics and questions from the audience.

##### **II. Topics for Discussion at the Public Meeting**

The following questions represent the kinds of topics that will be discussed at the meeting. The final questions to be discussed at each session will be available the day of the meeting.

1. Who is the likely intended use population for these devices and how will they be used in patient management? For example, will they be used for general hospital, surgical, critically ill, pediatric patients, etc.? What are the study considerations for evaluating the devices in these different populations?

2. How does the intended use of the device affect the design of the clinical studies and the evaluation and adequacy of device performance? For example, are the accuracy needs for a device used to monitor trends over time different from the accuracy needs of one where the individual glucose results are used to replace discrete glucose measurements? Is greater accuracy needed when the device is used in certain populations? What metrics can be used to evaluate whether or not results from these devices are sufficiently accurate and reliable for the proposed intended use(s)?

3. What conditions, medications, or therapies have the potential to cause interference and require evaluation? What kinds of studies/models are appropriate to evaluate interference?

4. Differences in glucose concentrations may be observed when testing arterial and venous blood samples from the same patient. How can the potential differences in blood glucose concentrations be addressed when conducting the clinical studies?

Dated: May 15, 2012.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2012-N-0437]

#### **International Capacity Building With Respect to Food Safety; Public Meeting; Request for Comments**

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

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA or Agency) is announcing a public meeting entitled "International Capacity Building With Respect to Food Safety." This public meeting will provide interested persons an opportunity to discuss FDA's comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States (the "capacity-building plan"). FDA is developing this plan under the Food Safety Modernization Act (FSMA). More specifically, the public will have an opportunity to provide information and share views that will inform FDA's development of the capacity-building plan. FDA is also establishing a docket to collect comments, data, and information relevant to the capacity-building plan.

*Date and Time:* See section III, "How to Participate in the Public Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management.

*Contact Persons:* For questions about registering for the meeting, to register orally, or to submit a notice of participation by mail, Fax, or email: Courtney Treece, Planning Professionals, Ltd., 1210 West McDermott, Suite 111, Allen, TX 75013, 704-258-4983, Fax: 469-854-6992, email: [ctreece@planningprofessionals.com](mailto:ctreece@planningprofessionals.com).

For questions about the content of the public meeting or if special accommodations are needed due to a disability, contact Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: [Juanita.Yates@fda.hhs.gov](mailto:Juanita.Yates@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**