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.

[FR Doc. 2012–12180 Filed 5–18–12; 8:45 am]

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.*

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.*

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Pub. L. 111–353) establishes the foundation for a modernized food safety system that provides FDA with more authorities to address the increasingly globalized food supply and prevent problems before they occur. The legislation comes at a time when FDA has identified strengthening the safety and integrity of the global supply chain as a key Agency priority. Indeed, two recent reports have focused on the challenges of global supply chains: FDA's ''Pathway to Global Product Safety and Quality,'' and the Institute of Medicine's report ''Ensuring Safe Foods and Medical Products through Regulatory Systems Abroad,'' which was commissioned by FDA. FSMA enhances FDA's efforts to increase the safety of the global supply chain, by, among other things, recognizing the importance of partnerships in the area of imports. Critically, the legislation directs FDA to focus on international food safety capacity—a key prevention-oriented activity. FSMA requires that the Secretary (by delegation, FDA) develop a plan to increase the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries in countries that export foods to the United States (Pub. L. 111–353, sec. 305). (To see the full text of section 305 of FSMA, visit: *http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm#SEC305.).*

Further, FDA is required to develop the capacity-building plan in consultation with certain stakeholders, including representatives of the food industry, foreign government officials, nongovernmental organizations that represent the interests of consumers, and certain Federal officials. The Federal officials include the Secretary of Agriculture, the Secretary of State, the Secretary of the Treasury, the Secretary of Homeland Security, the U.S. Trade Representative, and the Secretary of Commerce. FDA is also required to consult with other stakeholders.

The capacity-building plan must include, as appropriate:

1. Recommendations for bilateral and multilateral arrangements and agreements, including providing for responsibilities of exporting countries to ensure food safety;

2. Provisions for secure electronic data sharing;

3. Provisions for mutual recognition of inspection reports;

4. Training of foreign governments and food producers on U.S. requirements for safe food;

5. Recommendations on whether and how to harmonize requirements under the Codex Alimentarius; and

6. Provisions for multilateral acceptance of laboratory methods and testing and detection techniques.

The public meeting is an opportunity for interested persons and stakeholders to share views concerning how FDA should address the six elements in the capacity-building plan. Although section 305 identified these six elements, the list need not be exclusive. Therefore, interested persons may also share views as to whether FDA should consider additional issues in developing the plan. Furthermore, the public meeting is an opportunity for FDA to share the Agency's current thinking on the capacity-building plan. FDA encourages interested persons to provide feedback on any proposals that FDA presents at the public meeting. FDA is also establishing a docket to obtain comments, data, and evidence that will inform the Agency's development of the capacity-building plan. FDA will make available the agenda and other documents prior to the public meeting.

II. Purpose and Format of the Meeting

FDA is holding the public meeting to receive input from the public and from stakeholders to inform FDA's development of the capacity-building plan. This 1-day public meeting will open with a discussion of the context for international food safety capacity building and then proceed with more specific discussions about the capacity-building plan. Throughout the meeting, FDA will provide opportunities for individuals to share their views.

Prior to the public meeting, FDA will post the agenda for the meeting on the Agency's Web site. Interested persons may access the agenda at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.* In addition to posting the agenda, FDA may also make available additional information about the capacity-building plan at this Web site. For general information, interested persons may visit FDA's FSMA International Capacity Building Web page located at *http://www.fda.gov/Food/FoodSafety/FSMA/ucm301708.htm.*

III. How to Participate in the Public Meeting

Stakeholders and interested persons will have the opportunity to provide oral comments. The public meeting will be held from 9 a.m. to 5 p.m. on June 19, 2012, at the L'Enfant Plaza Hotel, 480 L'Enfant Plaza SW., Washington, DC The meeting is open to the public and on-site registration will be available, beginning at 8 a.m. However, attendees are encouraged to register in advance because seating is limited. Individuals who wish to attend the meeting can obtain information on how to register online at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.* There is no fee for registration.

Regardless of attendance at the public meeting, individuals may also share their views by submitting electronic or written comments to FDA's Division of Dockets Management. The deadline for submitting comments to the docket is July 20, 2012. Please note the following important dates:

- June 11, 2012: Closing date for advance registration and requesting special accommodations due to a disability.
- July 20, 2012: Closing date to submit either electronic or written comments to FDA's Division of Dockets Management.

IV. Request for Comments

When submitting electronic or written comments to FDA's Division of Dockets Management, please include the docket number found in brackets in the heading of this document. All comments received by the Agency may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts and Recorded Video

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and at FDA's FSMA Web site at: *http://www.fda.gov/Food/FoodSafety/FSMA/ucm301708.htm.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be video recording the public meeting. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at *http://www.fda.gov/Food/FoodSafety/FSMA/ucm301708.htm.*

Dated: May 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12209 Filed 5–18–12; 8:45 am]

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