- United States Pharmacopeia Chapter Development Impact
- Total Cost of Quality
- FDA New Inspectional Approach and Trends
- Supplier Selection and Due Diligence
- How to Operate in Different Regions of the World
- Establishing a Meaningful Supplier Qualification Program
- Supply Chain Development
- Finished Product Distribution Channel
- Enterprise Resource Planning
- Self Inspections & Corporate Audits
- Quality Agreements
- Business Process Management
- Global Standards Association Near Term Solutions

The conference includes:

- Deep Dive Lunch Sessions
- Live Polling Used by Speakers
- Case Studies
- Small Group Discussions
- Networking Lunch by Topic

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17077 Filed 7–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0622]

Regulatory Science Considerations for Medical Countermeasure Radiation Biodosimetry Devices

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 ''Regulatory Science Considerations for Medical Countermeasure (MCM) Radiation Biodosimetry Devices.'' The purpose of the public meeting is to obtain input from academia, Government, industry, and other stakeholders on the clinical application and scientific and technological challenges for performance validation of radiation biodosimetry devices.

Date and Time: The public meeting will be held on September 27 and 28, 2012, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* The public meeting will also be webcast.

Contact: Jennifer S. Dickey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4254, Silver Spring, MD 20993–0002, 301–796–5028, Fax: 301–847–8512, email: *Jennifer.Dickey@fda.hhs.gov.*

Registration: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this public meeting must register online by 4 p.m., September 13, 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 public 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 20993–0002, 301–796–5661, email: Susan.Monahan@fda.hhs.gov at least 7 days in advance of the meeting.

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, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see previous paragraph). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Persons interested in viewing the webcast must register online by 4 p.m., September 13, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 20, 2012. If you have never attended a Connect Pro meeting before, test your connection at: *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.* (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 public comment sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific 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. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin, and will select and notify participants by September 18, 2012. All requests to make oral presentations must be received by the close of registration on September 13, 2012 by 4 p.m. If selected for presentation, any presentation materials must be emailed to Jennifer Dickey (see *Contact*) no later than September 24, 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 the clinical application and scientific and technological challenges for performance validation of radiation biodosimetry devices. In order to permit

the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is October 12, 2012 (2 weeks after the public meeting).

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 topics as outlined in section III of this document, please identify the topic 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 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 transcript will also be available approximately 45 days after the public 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

In the event of an accident or terrorist attack that exposes a large population to radiation, an accurate assessment of the absorbed ionizing radiation dose received by victims will be essential for triage and medical management. Because there is currently no cleared or approved radiation biodosimeter for use in a mass exposure scenario, the development of proper radiation biodosimetry tools is a critical unmet public health need. However, because it is impossible to obtain samples that accurately reflect the intended use population of the device, validating the performance of radiation biodosimeters poses significant scientific and regulatory challenges. As such, FDA is holding this public meeting to obtain input from academia, Government, industry, and other stakeholders on the clinical application and scientific and technological challenges for performance validation of radiation biodosimetry devices. Individual perspectives from meeting participants may help to identify solutions for the scientific challenges associated with radiation biodosimetry development, and may clarify the regulatory path forward to ensure device safety and effectiveness and thereby provide significant clinical and public health benefits.

II. Meeting Overview

The public meeting will consist of the following: (1) Presentations providing background on anticipated uses of radiation biodosimetry medical countermeasure devices, (2) the device design and performance evaluation challenges identified by FDA, (3) specific technology considerations in radiation biodosimetry, (4) an open public comment session, and (5) an open discussion on topics identified by FDA and those raised by the presentations (see section III of this document). The purpose of this meeting is for participants to share individual perspectives during the discussions. FDA is not seeking group opinions, recommendations, or advice on any matter. Additional information, including a meeting agenda, will be available on the Internet immediately after publication of this document in the **Federal Register.** This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov.* This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select the appropriate meeting from the list.)

III. Topics for Discussion at the Public Meeting

The following questions represent the kinds of topics that will be discussed at the meeting.

1. Performance Evaluation for Radiation Biodosimetry:

A. What data would support the use of ex vivo radiation human samples in device performance validation?

B. What types of in vivo radiation human samples may be available to validate the performance of radiation biodosimeters?

C. What pre-clinical or clinical animal model testing might be necessary to demonstrate radiation biodosimeter performance?

D. Would a non-human primate pivotal clinical study be appropriate to support clearance/approval of biodosimetry MCM devices?

E. What data would support device applicability to both partial body and total body irradiation scenarios?

F. How should the impact of delays in sampling, delays in testing, combined injury, and other potential confounders on the performance of a radiation biodosimeter be assessed?

G. What challenges does the use of novel technologies bring to radiation biodosimetry development and performance validation?

2. Public Health Considerations for Radiation Biodosimetry:

A. What device design elements would address the need for rapid patient triage in a crisis scenario?

B. What device design elements should be included to account for the potential for high demand, device use by untrained medical personnel, and therapeutic decisionmaking based on limited resources?

C. What information should the Agency clarify in regards to the regulatory path forward for radiation biodosimetry MCM devices?

Dated: July 5, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17082 Filed 7–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0004]

Statement of Cooperation Between the Food and Drug Administration and the Secretaria of Health of the United Mexican States: Safety and Sanitary Quality of Fresh and Frozen Molluscan Shellfish Exported From Mexico to the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a Statement of Cooperation (SOC) between FDA and Secretariat of Health (SS) of the United Mexican States, through the Federal Commission for Protection from Sanitary Risks (COFEPRIS). The purpose of the SOC is to safeguard public health and to ensure the safety and sanitary quality of fresh