Designation programs, while the second will provide an overview of the FDA HUD Designation Program. Both morning sessions will also cover the Orphan Products Grant Program and the EU rare disease research programs as it relates to drugs and biologics, and devices, respectively. Both of these morning sessions will also be available by webcast.

The afternoon session will provide an opportunity for appropriately registered on-site participants to have one-on-one meetings with FDA or EMA staff members to discuss the specifics on how to apply for an orphan product grant, EU rare disease research assistance program, a HUD designation, or orphan drug designation. Participants requesting one-on-one meetings will need to undergo a second registration process with FDA, and are expected to bring information for at least one candidate orphan drug or device that holds promise for the treatment of a rare disease or condition in order to discuss the processes for putting together an application. In addition, participants of the HUD or orphan drug designation one-one-one sessions are highly encouraged to come prepared with a working draft submission of their particular promising therapy in order to maximize the utility of the one-on-one meetings. The FDA/EMA Orphan Product Designation and Grant Workshop is supported by the FDA and the EMA, and is being conducted in partnership with the European Organisation for Rare Disease (EURODIS), Genetic Alliance, and the National Organization for Rare Diseases (NORD).

Dated: August 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–21398 Filed 8–29–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0361]

Leveraging Registries With Medical Device Data for Postmarket Surveillance and Evidence Appraisal Throughout the Total Product Life Cycle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Leveraging Registries With Medical Device Data for Postmarket Surveillance and Evidence Appraisal Throughout the Total Product Life Cycle.'' The topic to be discussed is best practices for use of registries with medical device data for postmarket surveillance, clinical studies, and evidence appraisal.

DATES: The public workshop will be held on September 12, 2012, from 8 a.m. to 5 p.m. and September 13, 2012, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Greenbelt Marriott Hotel, 6400 Ivy Lane, Greenbelt, MD 20770, 301–441–3700.

FOR FURTHER INFORMATION CONTACT: Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4110, Silver Spring, MD 20993, 301–796–6689, email: *Danica.Marinac-Dabic@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m., September 10, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration will not be available on the day of the workshop.

If you need special accommodations due to disability, please contact Cynthia Garris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993, 301–796–5861, email: *cynthia.garris@fda.hhs.gov;* no later than September 5, 2012.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop 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 Danica Marinac-Dabic (see *Contact Person*). 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 Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m., September 5, 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 7, 2012.

Comments: FDA is holding this public workshop to obtain information on best practices for use of registries with medical device data for postmarket surveillance, clinical studies, and evidence appraisal. 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 workshop topics. The deadline for submitting comments related to this public workshop is October 10, 2012.

Regardless of attendance at the meeting, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. 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 public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

I. Background

Registries with medical device data collect data on patients who have been exposed to a medical device. Medical device postmarket surveillance presents unique challenges, related to the diversity and complexity of these products, the iterative nature of product development, the learning curve associated with technology adoption, and the relatively short, product life-cycle. For these reasons, FDA's Center for Devices and Radiological Health (CDRH) uses registries to assess the real-world performance of medical products and procedures; to determine the clinical effectiveness and safety of a test, medical device, procedure, or treatment; to describe the natural history of a problem or disease; and to examine trends of disease, treatment, or product use over time.

To be useful for postmarket device surveillance and assessment of benefits and risks, registries must contain sufficiently detailed patient, device, and procedural data and be linked to meaningful clinical outcomes. CDRH currently engages with more than a dozen registry efforts across a number of device areas, including cardiovascular, orthopedic, ophthalmic, and general surgery products. However, it is not practical or feasible to establish registries for each individual medical device. Development and maintenance of registries with medical device data and consortia of registries needs to be strategic, focused on product areas of high importance, utilize methodologies that integrate data collection into clinical practice, and maximize robust data collection while minimizing resource intensity.

CDRH believes that registry development in targeted product areas will both provide needed postmarket data to enhance public health and be cost-effective for industry, health care providers, and payers. In order to best leverage use of registries with medical device data, participation from all stakeholders, including other government Agencies, academia, professional societies, health care industry organizations, and patient and consumer groups, is needed. The purpose of the public workshop is to facilitate discussion among these key stakeholders in the scientific community on issues related to best practices for medical device registries for use across the Total Product Life Cycle. This public workshop is open to all interested parties. The target audience is professionals in general (academic, healthcare, payers, industry) interested in leveraging registries with medical device data as data and infrastructure for surveillance and studies.

II. Topics for Discussion at the Public Workshop

We intend to discuss a large number of issues at the public workshop, including but not limited to the following: (1) Current utilization of registries with medical device data; (2) use of registries with medical device data for postmarket surveillance; (3) registries in relation to the Sentinel provision in the FDA Safety and Innovation Act calling for the expansion of the postmarket risk identification and analysis system to include devices; (4) challenges and opportunities for using registries with medical device data for regulated studies; (5) best practices for governance and structure of registries; (6) business models for sustainable efforts; and (7) strategies and priorities for future use of registries with medical device data.

Dated: August 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–21437 Filed 8–27–12; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0913]

Medical Countermeasures for a Burn Mass Casualty Incident

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for abstracts for poster presentation.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Medical Countermeasures (MCM) for a Burn Mass Casualty Incident.'' The purpose of this public workshop is to describe medical countermeasure requirements for burn injuries of radiological, nuclear, or chemical origin in a scarce resources environment; identify gaps in the product landscape so as to articulate a consensus-based needs assessment; discuss testing approaches and regulatory pathways; and to educate workshop attendees on the concept of medical utilization and response integration. The overall goal is to engage stakeholders across the public and private sector in strategic dialogue related to development, evaluation, deployment, and monitoring of medical countermeasures to mitigate the adverse health consequences arising from public health emergencies, specifically those involving radiological, nuclear, or chemical threats.

Date and Time: The public workshop will be held on September 27, 2012, from 8:30 a.m. to 5 p.m. and September 28, 2012, from 8:30 a.m. to 12 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503A), 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.*

Contact: Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G439, 301–796–6970, Fax: 301–847–8507, email: *Suzanne.Schwartz@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on September 21, 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 permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Cindy Garris, email: *Cynthia.garris@fda.hhs.gov* or phone: 301 796–5861 no later than September 21, 2012.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop 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 Suzanne Schwartz to register (see *Contact*). 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 Workshop: This public workshop will