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

also be webcast. Persons interested in viewing the webcast must register online by 5 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 21, 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.* 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 Poster Presentations: This public workshop will include a poster session. During online registration you may indicate if you wish to present an abstract during the poster session. FDA has identified general topics in this document. FDA will do its best to accommodate requests for poster presentation and will select and notify participants by September 7, 2012. All abstract submissions for poster presentations must be emailed to Suzanne Schwartz (see *Contact*) no later than 5 p.m. on August 31, 2012. No commercial promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain information on medical countermeasures for a burn mass casualty incident. 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 workshop topics. The deadline for submitting comments related to this public workshop is October 31, 2012. However, only comments received prior to August 31, 2012 will be incorporated into the workshop while comments received after that date will be reviewed by FDA after the conclusion of the workshop.

Regardless of attendance at the public workshop, 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 II 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 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.)

SUPPLEMENTARY INFORMATION:

I. Background

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) was established by the Department of Health and Human Services (HHS) in 2006 as a Federal inter-Agency coordinating body responsible for providing recommendations to the Secretary of HHS on medical countermeasure priorities, development and acquisition activities, and strategies for distributing and using medical countermeasures held in the Strategic National Stockpile (SNS) to prevent or mitigate potential health effects from exposure to chemical, biological, radiological, and nuclear agents and other terrorist threats. The PHEMCE mission is therefore to advance national preparedness for natural, accidental, and intentional threats by coordinating medical countermeasure-related efforts within HHS and in cooperation with PHEMCE inter-Agency partners.

The 2012 PHEMCE Strategy has established the following 4 goals over the next 5 years: (1) Identify, create, develop, manufacture, and procure critical medical countermeasures; (2) establish and communicate clear regulatory pathways to facilitate medical countermeasures development and use; (3) develop logistics and operational plans for optimized use of medical countermeasures at all levels of response; and (4) address medical countermeasure gaps for all sectors of the American population. This is a complex mission space and many Federal Agencies, including FDA, have responsibilities that are critical to its success.

FDA is hosting this public workshop to address topics specific to national preparedness for a burn mass casualty incident of radiological, nuclear, or chemical origin. The blast and subsequent fires from such weapons could inflict serious thermal burns. With respect to a nuclear detonation, these injuries could affect hundreds to thousands of people. In such an attack, stabilizing individuals with burns and concomitant injuries becomes an immediate priority. Medical care for burns in a mass casualty incident would require the ready availability of large quantities of medical countermeasures for resuscitation, wound management, pain relief, and nutritional- and airway/breathing support in the initial post-injury period. The overall response is further complicated by the complex, expensive, and resource-intensive needs that extend over the longer-term treatment period for serious burns compounded by burn care expertise being in short supply.

There are approximately 1,850 burn beds in 126 burn units across the United States. The American Burn Association estimates that 700–800 of these beds may be occupied at any given time. To respond to a mass casualty incident such as a nuclear detonation—whereupon an estimated 10,000 or more individuals could require specialized burn care—patients may need to be transferred to specialized burn centers throughout the country because there may be relatively few dedicated burn beds available in the region. Also, patients may need to be treated in other care sites, such as local or regional trauma centers, if specialized burn centers are filled to capacity. The short supply of specialized burn experts and facilities may need to be considered one driver in regard to burn care product(s) design and development, enabling versatile use in the hands of nonspecialists as well.

II. Topics for Discussion at the Public Workshop

The workshop sessions will focus on the following general topics: Product (drug, device, biologic, and combination products) development challenges; clinical study design considerations for new products; regulatory pathways to market; challenges related to the organization and delivery of burn care

in disaster management (including medical utilization and response integration); FDA's role in coordination with the Centers for Disease Control and Prevention for deployment of assets in SNS; protecting the public from counterfeit as well as nonregulated ineffective products; FDA's responsibility for developing and implementing strategies to assess, evaluate and monitor medical countermeasure safety, performance, and patient compliance during and after a burn mass casualty incident; and a discussion of specific medical countermeasure needs for at-risk individuals.

Dated: August 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–21400 Filed 8–29–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

60-Day Proposed Information Collection: Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form; Request For Public Comment

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: 0917–0034, ''Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form.'' *Type of Information Collection Request:* Extension without revision of the currently approved information collection, 0917–0034, ''IHS Sharing What Works—BPPPLE Form,'' which was previously approved under the title ''Director's 3 Initiative Best Practice, Promising Practice, and Local Efforts Form.'' Although the name of the form has changed, the contents of the form remain the same. *Forms:* IHS Sharing What Works—BPPPLE Form (OMB Form No. 0917–0034). *Need and Use of Information Collection:* The IHS goal is to raise the health status of the American Indian and Alaska Native (AI/AN) people to the highest possible level by providing comprehensive health care and preventive health services. To support the IHS mission and to provide the product/service to IHS, Tribal, and Urban (I/T/U) programs, the Office of Preventive and Clinical Services' (OCPS) program divisions (i.e., Behavioral Health (BH), Health Promotion/Disease Prevention (HP/DP), Nursing, and Dental) have developed a centralized program database of Best/Promising Practices and Local Efforts (BPPPLE) and resources. The purpose of this collection is to develop a database of BPPPLE and resources to be published on the IHS.gov Web site which will be a resource for program evaluation and for modeling examples of various health care projects occurring in AI/AN communities.

All information submitted is on a voluntary basis; no legal requirement exists for collection of this information. The information collected will enable the Director's Three Initiative program to: (a) Identify evidence based approaches to prevention programs among the I/T/Us when no system is currently in place, and (b) Allow the program managers to review BPPPLE occurring among the I/T/Us when considering program planning for their communities.

Affected Public: Individuals. *Type of Respondents:* I/T/U programs' staff. The table below provides: Types of data collection instruments, Number of respondents, Responses per respondent, Average burden hour per response, and Total annual burden hour(s).

ESTIMATED BURDEN HOURS

Data collection instrument(s)	Number of respondents	Responses per respondent	Average burden hour per response	Total annual burden hours
IHS Sharing What Works—BPPPLE Form (OMB Form No. 0917–0034)	100	1	20/60	33.3
Total	100	.....	.....	33.3

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimates are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send Comments and Requests for Further Information: Send your written comments, requests for more information on the proposed collection, or requests to obtain a copy of the data collection instrument(s) and instructions to: Tamara Clay, IHS Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852–1627; call non-toll free (301) 443–4750; send via facsimile to (301) 443–9879; or send your email requests, comments, and return address to: *tamara.clay@ihs.gov.*

Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

Dated: August 24, 2012.

Yvette Roubideaux,

Director, Indian Health Service.

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