MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *NDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss data submitted by MSD Consumer Care, Inc. to support new drug application (NDA) 202211, for the partial switch from prescription to over-the-counter (OTC) of the oxybutynin transdermal system (proposed trade name OXYTROL FOR WOMEN). The proposed OTC use is ''treats overactive bladder in women.'' The data to be discussed will include a summary of the postmarketing experience with the oxybutynin transdermal system, and the results of consumer studies, including label comprehension studies, self-selection studies, and an actual use study. The committee will be asked to consider whether the data support the appropriate and safe use of oxybutynin transdermal system by OTC consumers.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 26, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 18, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 19, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Glendolynn S. Johnson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 24, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–21425 Filed 8–29–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration/European Medicines Agency Orphan Product Designation and Grant Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting: Food and Drug Administration/European Medicines Agency Orphan Product Designation and Grant Workshop. This 1-day workshop is intended to provide valuable information about the FDA and European Medicines Agency (EMA) Orphan Drug Designation programs, the FDA Humanitarian Use Device (HUD) Designation program, the FDA Orphan Products Grant program, and the European Union (EU) rare disease research programs to participants representing pharmaceutical, biotechnology, and device companies, as well as academics.

Date and Time: The meeting will be held on October 12, 2012, 8:30 a.m. to 5:30 p.m.

Attendance: Online registration for the workshop will be limited to 240 participants for the morning session, of which approximately 30 teams (up to 90 participants) may register for the one-on-one sessions. There will be no registration fee for the workshop.

Location: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD 20993–0002. 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.* For participants who cannot attend the morning meetings, simultaneous live interactive Webcasts will be made available. Participants may access the drug and biologics webcast by visiting the following site: *https://collaboration.fda.gov/orphan2012/.* The medical devices webcast can be accessed by visiting: *https://collaboration.fda.gov/devices2012/.*

Contact: Erica K. McNeilly at *Erica.McNeilly@fda.hhs.gov* or J. Lloyd Johnson at *Lloyd.Johnson@fda.hhs.gov*, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5279, Silver Spring MD 20993–0002, (301) 796–8660, FAX: (301) 847–8621.

Registration: Interested participants may register for this meeting at the following Web site: *https://events-support.com/events/FDA-EMA_Workshop.* If you need sign language interpretation during this meeting, please contact Erica K. McNeilly at *Erica.McNeilly@fda.hhs.gov* by September 28, 2012.

The workshop will consist of two simultaneous morning sessions. The first will provide an overview of the EMA and FDA Orphan Drug

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.)