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, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants by September 4, 2012. All requests to make oral presentations must be received by August 31, 2012. Any presentation materials must be emailed (see *Contact Person*) no later than September 5, 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 solicit public feedback regarding the medical device postmarket surveillance system in the United States. 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 meeting topics. The deadline for submitting comments related to this meeting is October 9, 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 meeting on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting from the posted events list.)

I. Background

FDA's Center for Devices and Radiological Health (CDRH) is responsible for protecting the public health by assuring the safety and effectiveness of medical devices and safe radiation-emitting products. A key part of this mission is to monitor medical devices and radiological products for continued safety and effectiveness after they are in use and to help the public get the accurate, science-based information they need to improve their health.

Several high-profile device performance concerns have led some to question whether CDRH's current postmarket surveillance system is optimally structured to meet the challenges of rapidly evolving medical devices and the changing nature of health care delivery and information technology. In their report entitled ''Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years'' published in July 2011, the Institute of Medicine recommended that FDA develop and implement a comprehensive medical device postmarket surveillance strategy to collect, analyze, and act on medical device postmarket performance information. As part of the process of developing and implementing this strategy, FDA is holding a public meeting to discuss the current and future state of medical device postmarket surveillance. Prior to this public meeting, FDA intends to issue a preliminary report on CDRH's plan to strengthen the medical device postmarket surveillance system in the United States. FDA intends to solicit public feedback regarding the report contents.

II. Topics for Discussion at the Public Meeting

We intend to solicit public feedback regarding the medical device postmarket surveillance system in the United States. Specific topics of interest include, but are not limited to, the following: (1) The unique device identifier system and its incorporation into health-related electronic records; (2) national and international device registries for selected products; (3) adverse event reporting and analysis; and (4) developing and using new methods for evidence generation synthesis and appraisal. These topics will also be discussed 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. Key questions for feedback include:

- Are these the right efforts?
- What principles should drive these efforts?
- What are the attributes of an effective ''active surveillance'' system for devices?
- How can the device active surveillance system leverage existing systems (e.g., Sentinel)?

Following public comment, FDA intends to have a moderated discussion session regarding strengthening the national medical device postmarket surveillance system.

Dated: August 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–21434 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–0001]

Nonprescription Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Nonprescription Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 9, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301–589–5200.

Contact Person: Glendolynn S. Johnson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring,

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