

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 June 6, 2013. 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 June 10, 2013.

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 AnnMarie Williams, Committee Management Staff, at 301-796-5966 or [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov) 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: May 17, 2013.

**Jill Hartzler Warner**,  
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-12230 Filed 5-22-13; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

#### Drug Safety and Risk Management 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:* Drug Safety and Risk Management 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 July 10, 2013, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>;

under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [DSaRM@fda.hhs.gov](mailto:DSaRM@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 Food and Drug Administration Amendments Act of 2007 requires FDA to bring, at least annually, one or more drugs with Risk Evaluation and Mitigation Strategies (REMS) with elements to assure safe use (ETASU) before its Drug Safety and Risk Management Advisory Committee (DSaRM). On July 10, 2013, the Agency plans to discuss the risk management of LOTRONEX (alosetron hydrochloride) tablets, by Prometheus Laboratories Inc., which is approved for the treatment of women with severe diarrhea predominant irritable bowel syndrome (IBS-d). The Agency will seek the committee's comments as to whether the REMS with ETASU for this drug

assures safe use, is not unduly burdensome to patient access to the drug, and to the extent practicable, minimizes the burden to the health care delivery system.

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 June 25, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. to 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 June 17, 2013. 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 June 18, 2013.

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

Dated: May 17, 2013.

**Jill Hartzler Warner,**  
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-12226 Filed 5-22-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request: Generic Clearance To Support Programs and Administrative Operations at the National Cancer Institute (NCI)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have

practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*To Submit Comments and For Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Vivian Horovitch-Kelley, PRA/OMB Project Clearance Liaison, Office of Management Policy and Compliance (OMPC), National Cancer Institute, 11400 Rockville Pike, Room 707, Rockville, MD 20852 or call non-toll-free number 301-480-0541 or Email your request, including your address to: [Horovitchkellv@mail.nih.gov](mailto:Horovitchkellv@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

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

*Proposed Collection:* Generic Clearance to Support Programs and Administrative Operations At the National Cancer Institute (NCI), 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* This is a request for a new, generic submission that would be used for administrative and program-related submissions. Administrative submissions are defined as information collections (ICs) wherein the primary content is used for administrative purposes (e.g., an application) or to monitor or improve a program. These ICs may involve little if any, subsequent analysis and/or the use of simple, descriptive statistics. Some ICs are forms used to source and aggregate contact information, history, preferences, opinions, and/or other data that does not necessitate further inquiry but allow the respondents to maintain contact, indicate preferences, and respond to data calls of information that has not already been collected. Other ICs may be program-related requests for the purpose of monitoring, improving or assessing the effectiveness of the program. NCI program staff who have submitted sub-projects that have been reviewed and returned by OMB, have contributed ideas and comments to this request. Along with the analysis, NCI's ongoing education and outreach effort has increased the awareness and the need for the request of a generic, administrative and program-related information collection. NCI's current scope and capacity for administrative generic sub-studies is non-existent and this request would fill this gap.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 5,000.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Category of respondents	Number of respondents	Frequency of responses	Average time per response (in hours)	Total burden hours
Individuals, Households, Private Sector, State Government, Local Government, Tribal Government, or Federal Government .....	6,000	1	50/60	5,000

Dated: May 17, 2013.

**Vivian Horovitch-Kelley,**  
NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2013-12276 Filed 5-22-13; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR10-169: Academic Industrial Partnership.

*Date:* June 18-19, 2013.

*Time:* 9:00 a.m. to 5:00 p.m.