

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-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 (DSaRM) 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 18, 2014, from 9 a.m. to 4 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), 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:* Kristina Toliver, 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: [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 committee will discuss the Food and Drug Administration

Amendments Act of 2007 which 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 the DSaRM Advisory Committee. The Agency plans to discuss the risk management of eculizumab (SOLIRIS). The Agency will seek public input whether the REMS with ETASU for this drug assures safe use of the drug, is not unduly burdensome on patient access to the drug, and to the extent practicable, minimizes the burden on 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 November 3, 2014. 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 24, 2014. 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 27, 2014.

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 Kristina Toliver 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: October 2, 2014.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2014-24002 Filed 10-7-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-0001]

**Science Board to the Food and Drug Administration 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:* Science Board to the Food and Drug Administration (Science Board).

*General Function of the Committee:* The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda, and advice on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs.

*Date and Time:* The meeting will be held on Wednesday, November 19, 2014, from approximately 8:30 a.m. to

5:30 p.m., and Thursday, November 20, 2014, from approximately 8:30 a.m. to 12:45 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Sections B and C, Silver Spring, Maryland 20993. For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at <https://collaboration.fda.gov/scienceboard>. 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:* Martha Monser, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, Bldg. 32, Rm. 4286, 10903 New Hampshire Ave., Silver Spring, Maryland 20993, 301-796-4627, [martha.monser@fda.hhs.gov](mailto:martha.monser@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:* On November 19, 2014, the Science Board will review the existing nonclinical and clinical data related to the use and potential toxicity of anesthetics and sedation drugs in the pediatric population. The Science Board will be asked to make recommendations on steps the FDA should take to further evaluate and to mitigate the risks associated with the use of these drugs in the pediatric population and mechanisms to best communicate with the public regarding this issue.

On November 20, 2014, the Science Board will be provided with progress reports from two subcommittees, the Commissioner's Fellowship Program Evaluation subcommittee and the Science Moving Forward subcommittee. The Board will be asked to support the formation of a new subcommittee to evaluate the Office of Regulatory Affairs' current investments in the Food

Emergency Response Network cooperative agreement program and funding for state laboratories to achieve International Organization for Standardization accreditation. The Board will also be asked to support the formation of a new subcommittee to evaluate the Centers of Excellence in Regulatory Science and Innovation program. A recipient of one of the fiscal year 2013 Scientific Achievement Awards (selected by the Board) will provide an overview of the activities for which the award was given.

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 link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions pertaining to issues before the Board on November 19, 2014, may be made to the contact person on or before Wednesday, November 12, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 19, 2014. 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 Tuesday, November 4, 2014. 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 at the November 19, 2014, meeting by Wednesday, November 5, 2014.

Written submissions pertaining to issues before the Board on November 20, 2014, may be made to the contact person on or before Thursday, November 13, 2014. Oral presentations from the public will be scheduled between approximately 12 p.m. and

12:30 p.m. on November 20, 2014. 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 Wednesday, November 5, 2014. 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 at the November 20, 2014, meeting by Thursday, November 6, 2014.

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 Martha Monser 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: October 2, 2014.

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0967]

### Prescription Drug User Fee Act Patient-Focused Drug Development; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.