

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2016-N-0001]

Risk Communication Advisory Committee; Notice of Meeting**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Risk Communication Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on November 7, 2016, from 8:30 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Natasha Facey, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3354, Silver Spring, MD 20993-0002, 301-796-5290, Natasha.Facey@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.

SUPPLEMENTARY INFORMATION:

Agenda: On November 7, 2016, the committee will discuss and make recommendations on FDA's draft Strategic Plan for Risk Communication and Health Literacy. The purpose of the Strategic Plan for Risk Communication

and Health Literacy is to clarify how the Agency can communicate the benefits and risks of FDA-regulated products to target audiences more effectively, and so promote better informed decision making. The committee will also hear presentations on some of FDA's external communications and how these communications relate to the draft Strategic Plan for Risk Communication and Health Literacy.

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 1, 2016. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2:30 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 21, 2016. 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 25, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Sheryl Clark at Sheryl.Clark@fda.hhs.gov or 240-402-5273 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: September 13, 2016.

Janice Soreth,*Acting Associate Commissioner, Special Medical Programs.*

[FR Doc. 2016-22553 Filed 9-19-16; 8:45 am]

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[Docket No. FDA-2016-N-2648]

Announcement of Requirements and Registration for the 2016 Food and Drug Administration Naloxone App Competition**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the 2016 FDA Naloxone App Competition (Competition), a prize competition under the America COMPETES Reauthorization Act of 2010 (COMPETES Act). The Competition is an effort to help reduce deaths associated with prescription opioid and heroin overdose by seeking innovative approaches to help reduce preventable harm associated with opioids. Specifically, the goal of this Competition is to spur innovation around the development of a low-cost, scalable, crowd-sourced mobile phone application that helps increase the likelihood that opioid users, their immediate personal networks, and first responders are able to identify and react to an overdose by administering naloxone, a medication that reverses the effects of opioid overdose.

DATES: The Competition begins September 20, 2016.

1. Registration for the Competition: September 23 to October 7, 2016
2. Naloxone App Code-a-Thon: October 19 and October 20, 2016
3. Submission Period: September 23 to November 7, 2016