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 committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 17, 2017, will be provided to the committees. 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 6, 2017. 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 10, 2017.

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 special accommodations due to a disability, please contact Kalyani Bhatt 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 *https://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 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21170 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0502]

Range of Risk Evaluation and Mitigation Strategies Platform Standards Initiative: Needs Assessment; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is seeking public input on the design of the REMS Platform Standards Initiative, as well as methods and best practices for its construction. To facilitate this, FDA is making available the ''REMS Platform Standards Initiative: Needs Assessment'' (needs assessment), which summarizes a range of risk evaluation and mitigation strategies (REMS) activities that could be standardized and integrated into the health care system through the use of electronic data standards.

DATES: The comment period will be open indefinitely.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0502 for ''REMS Platform Standards Initiative: Needs Assessment; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the

docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Adam Kroetsch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1168, Silver Spring, MD 20993–0002, 301–796–3842, *REMS_Standardization@fda.hhs.gov;* or Aaron Sherman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 240–402–0493, *REMS_Standardization@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 5, 2015, FDA launched the REMS Platform Standards Initiative (previously referred to as the ''Common REMS Platform Initiative''), with the goal of developing and leveraging electronic health data standards, referred to as ''REMS platform standards,'' to further standardize certain activities associated with REMS with elements to assure safe use (ETASU), and integrate them into existing health care systems. (Information about the initiative can be found at: *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM507451.pdf*). Since then, FDA has been working to determine the most effective methods for carrying out this initiative, including how best to engage the public on the project and advance the development of REMS platform standards. To achieve these ends, FDA is publishing the ''REMS Platform Standards Initiative: Needs Assessment,'' which seeks to provide REMS stakeholders, standards developers, and health information technology (IT) systems developers with specific, detailed information on the areas in which standards development is needed and the information that the data standards would need to communicate to effectively carry out REMS activities. FDA seeks comment on the document as a whole, as well as on the specific questions that follow.

(1) Does this needs assessment cover all of the REMS activities for which standards development would be beneficial?

(2) Which REMS activities should be given highest priority for standards development?

(3) What standards already exist that could be used to address the needs and facilitate the REMS activities described in the needs assessment?

(4) Where (if at all) do new standards need to be developed?

(5) What other opportunities exist to leverage health IT to facilitate the completion of REMS activities?

FDA hopes that the needs assessment will help identify areas where standards development projects to support REMS are already underway, as well as areas that are ripe for standards development, enabling interested stakeholders to engage further in this project.

What is the REMS Platform Standards Initiative?

The goal of the REMS Platform Standards Initiative is to leverage electronic health data standards to standardize certain activities in REMS with ETASU and integrate them into health IT systems. Under the initiative, FDA seeks to work with third-party standards development organizations to encourage the development of electronic data standards that may be used to facilitate communication between REMS and their participants. Once the standards are developed, FDA would maintain a list of REMS platform standards, encourage their use in REMS with ETASU, and encourage the development of tools that use these standards to integrate REMS into health care providers' existing systems.

Why is FDA launching the REMS Platform Standards Initiative?

This initiative was launched for a number of reasons. Stakeholders have requested a centralized method to enroll in and interact with REMS with ETASU and more fundamental standardization of REMS architecture. There is also a need for a comprehensive set of standards for REMS to help minimize REMS burden on the health care delivery system and integrate REMS into health IT systems.

The goal of the REMS Platform Standards Initiative is to give all stakeholders—including sponsors, data vendors, clinical decision support system developers (such as those for hospitals, private practices, etc.)—a ''fixed target'' for standardization and integration. If successful, this will clarify how sponsors can develop standardized REMS that are more easily integrated into the health care system and what health care providers must do to comply with those REMS. Ultimately, REMS that are more effectively standardized and integrated into the health care system should facilitate enhanced compliance and safer use of drugs that have REMS.

II. Electronic Access

Persons with access to the Internet may obtain the needs assessment at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM565594.pdf.*

Dated: September 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–21218 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: National Institute of Child Health and Human Development Special Emphasis Panel NICHD Education Grants.

Date: November 6, 2017.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joanna Kubler-Kielb, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–7510, 301–435–6916, *kielbj@mail.nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, SPROUTS: Development of eating behaviors in early childhood.

Date: November 13, 2017.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.