correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Operating and maintenance costs
Request for CLIA categorization	60	15	900	1	900	$46,800

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour ($52 \times 900$), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (e.g. paper).

Dated: May 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12099 Filed 5–21–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0502]

Standardizing and Evaluating Risk Evaluation and Mitigation Strategies; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 2-day public meeting to obtain input on issues and challenges associated with the standardization and assessment of risk evaluation and mitigation strategies (REMS) for drug and biological products. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA has committed to standardizing REMS to better integrate them into, and reduce their burden to, the existing and evolving health care system. As part of the PDUFA commitments, FDA will also seek to develop evidence-based methodologies for assessing the effectiveness of REMS.

To obtain input from stakeholders about REMS standardization and evaluation, FDA will hold a public meeting to give stakeholders, including health care providers, prescribers, patients, pharmacists, distributors, drug manufacturers, vendors, researchers, standards development organizations, and the public an opportunity to provide input on ways to standardize and assess REMS.

DATES: The meeting will be held on July 25 and 26, 2013, from 8:30 a.m. to 4:30 p.m. Individuals who wish to present at the meeting must register by July 10, 2013. See section IV of this document for information on how to register to speak at the meeting.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify each set of comments with the corresponding docket number for the public meeting as follows: ''Docket No. FDA–2013–N–0502, ''Standardization and Evaluation of Risk Evaluation and Mitigation Strategies, Public Meeting.''

FOR FURTHER INFORMATION CONTACT: Adam Kroetsch, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993, 301–796–3842, FAX: 301–847–8443, email: *REMS_Standardization@fda.hhs.gov.*

I. Background

This meeting builds upon prior stakeholder feedback on and input into the design, implementation, and assessment of REMS. In July 2010, FDA held a public meeting to obtain input on issues associated with the development and implementation of REMS. In June 2012, FDA held a public workshop to discuss survey methodologies and instruments that can be used to evaluate patients' and health care providers' knowledge about the risks of drugs marketed with an approved REMS. In addition, the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) requires FDA to bring, at least annually, one or more drugs with REMS with elements to assure safe use (ETASU) before the Drug Safety and Risk Management Advisory Committee. FDA also regularly discusses both pre- and postapproval REMS with ETASUs with various FDA advisory committees in the context of specific applications.

This meeting also builds on FDA's internal efforts to improve the design, implementation and assessment of REMS. In 2011, FDA created the REMS Integration Initiative, designed to evaluate and improve its implementation of REMS authorities. More information about the REMS Integration Initiative can be found at (*http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm350852.htm*). As part of this effort, FDA seeks to improve future REMS assessments and incorporate the latest methodologies in the evolving science of risk management. In its February 2013 report, ''FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety,'' the Department of Health and Human Services Office of the Inspector General affirmed the need to identify and implement reliable methods to assess the effectiveness of REMS and REMS components. This report is available at *https://oig.hhs.gov/oei/reports/oei-04-11-00510.pdf.*

This public meeting is intended to meet performance goals included in the fifth reauthorization of the Prescription Drug User Fee Act (PDUFA V). This reauthorization, part of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) signed by the President on July 9, 2012, includes a number of performance goals and procedures that are documented in the PDUFA V

Commitment Letter. (See ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017,'' which is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf*.)

FDA developed the performance goals and procedures for PDUFA V in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders from July 2010 through May 2011. Title XI of the letter, ''Enhancement and Modernization of the FDA Drug Safety System,'' states that FDA user fees will be used to enhance REMS by measuring the effectiveness of REMS and evaluating, with stakeholder input, appropriate ways to better integrate them into the existing and evolving health care system. (See ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf*).

Toward that end, the PDUFA V Commitment Letter identified a number of specific goals, including holding one or more public meetings to explore strategies to standardize REMS and reduce the burden of implementing REMS on practitioners, patients, and others in various health care settings and on methodologies for assessing whether REMS are mitigating the risks they purport to mitigate and for assessing the effectiveness and impact of REMS, including methods for assessing the effect on patient access, individual practitioners, and the overall burden on the health care delivery system. FDA also committed to issuing a report of its findings regarding standardizing REMS; the report will identify priority projects in four areas (pharmacy systems, prescriber education, providing benefit/risk information to patients, and practice settings). FDA also committed to issuing guidance on methodologies for assessing REMS, specifically, methodologies for determining whether a specific REMS with ETASU is commensurate with the specific serious risk listed in the labeling of the drug and considering the observed risk, not unduly burdensome on patient access to the drug. For details on specific FDA commitments, see the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017, Section XI, ''Enhancement and Modernization of the FDA Drug Safety System,'' Parts A2, A3, which is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf*.

II. Purpose and Scope of Meeting

The purpose of this public meeting is to obtain feedback from stakeholders on: (1) Issues and challenges associated with standardizing and assessing REMS for drug and biological products and (2) identifying potential projects that will help standardize REMS and integrate them into the health care delivery system. FDA is seeking information and comments from a broad range of stakeholders, including interested health care providers, prescribers, patients, pharmacists, distributors, drug manufacturers, vendors, researchers, standards development organizations, and the public.

To promote greater standardization and improved assessment of REMS, FDA is seeking feedback on how to reduce any unnecessary variation in REMS and, in the process, to make REMS elements and associated tools less burdensome to stakeholders, better integrated into the health care system, more effective, and easier to assess. FDA recognizes that the REMS elements and associated tools found in existing REMS programs have varied. In some cases, these variations are appropriate, because REMS are designed to address specific risks posed by particular drugs in a wide range of patient populations and health care settings. However, FDA may be able to establish standards to reduce unnecessary variation and to make REMS more predictable and simpler to understand, implement, and measure. The establishment of standards also presents the opportunity to improve upon the design of REMS elements and associated tools and assessment methodologies in the future.

After this meeting, FDA will issue a report to the public that identifies REMS standardization projects in the four areas specified in the PDUFA V commitment letter: Prescriber education, pharmacy systems, practice settings, and providing benefit/risk information to patients. FDA welcomes stakeholder input to help identify high-quality projects that could offer FDA and stakeholders the opportunity to develop, test, and implement new approaches to standardizing REMS and integrating them into the health care system. The scope of such projects might include research studies, demonstration projects, and the development of new REMS tools using, for example, emerging information technologies or existing controls in the health care system. These projects might be carried out by FDA alone or in collaboration with stakeholders and outside experts.

III. Scope of Public Input Requested

FDA is particularly interested in obtaining information and public comment on the following areas:

A. Prescriber-Directed REMS Tools

REMS programs use a number of tools to educate prescribers and/or ensure that they carry out REMS requirements, including screening, monitoring, and counseling patients. These tools have included risk communications to prescribers, prescriber training, and instruments to help prescribers prescribe the drug safely—for example, counseling guides and checklists.

1. Many REMS with elements to assure safe use provide for prescriber training on the risks of the drug and how to use the drug safely. In some REMS, the completion of this training is required before a person can become a certified prescriber of the drug. Sponsors provide REMS training in a variety of formats, including in-person, online, and through printed materials. FDA is interested in input on which formats and training approaches are most effective for prescriber training; how frequently prescribers should be asked to take REMS training and whether a single training is sufficient; what additional tools could be used to reinforce what prescribers learn during the training and help them apply what they have learned; and how REMS training could be incorporated into continuing medical education programs.

2. Prescriber training often includes knowledge assessments that prescribers must successfully complete as part of the training. These knowledge assessments, which typically take the form of multiple-choice questions, are designed to ensure that the prescriber understands the training material; they also serve to reinforce key messages from the training. (Knowledge assessments should not be confused with the surveys of knowledge that drug manufacturers may conduct as part of their REMS assessments.) FDA is interested in input on when knowledge assessments should be included in REMS and whether they should be included in all REMS that include prescriber training. In addition, FDA requests input on how knowledge assessments can be designed to ensure accurate measurement of prescribers' knowledge and how knowledge assessments can be designed to measure or predict prescribers' ability to apply what they have learned in their practice.

3. Once prescribers have met all requirements for certification under the

REMS (e.g., completed training), they generally must complete an enrollment form to be recognized as certified and able to prescribe the drug. Generally, by completing, signing, and submitting the enrollment form, prescribers acknowledge their understanding of the drug's risks and the REMS requirements. In some REMS, the enrollment form also is used to share information about the risks of the drug and how to use the drug safely. FDA is interested in stakeholder input on whether the information and agreements included in current REMS prescriber enrollment forms are presented in a way that is easy for prescribers to understand. Also, what, if anything, should be done to standardize, simplify, or streamline prescriber enrollment forms and the overall prescriber enrollment process?

4. What else can be done to improve the effectiveness of existing prescriber-directed REMS tools, to standardize them, to reduce their burden, and/or to better integrate them into the health care delivery system?

5. What tools and technologies not currently used in REMS could be incorporated into REMS to help educate prescribers and ensure that they carry out REMS requirements? What evidence exists to support the effectiveness of these tools and technologies?

6. What projects could be carried out to standardize the provision of prescriber education in REMS?

7. What projects could be carried out to better integrate REMS into prescriber practice settings?

8. What methodologies exist or might be developed to assess the effectiveness of prescriber-directed REMS tools, the tools' burden on the health care delivery system, and the effect of these tools on patient access?

B. Patient-Directed REMS Tools

REMS programs may use a number of tools to educate and counsel patients, provide patients with information about the risks of the drug, and help to ensure that patients use the drug safely. These tools may include patient enrollment in the REMS, patient monitoring, counseling by health care professionals, Medication Guides, and other patient-directed educational materials.

1. REMS use a range of written materials to help educate and counsel patients, including Medication Guides. In some cases, health care practitioners give these materials to patients to read on their own, and in other cases health care providers are asked to review these materials with patients and use them in patient counseling.

2. In REMS that include patient education, what would make written educational materials more effective? What other materials, tools, and technologies, (e.g., reference materials, checklists, smartphone applications) might be used to help educate patients and reinforce what they have learned?

3. How could the provision of information to patients be standardized, and what are the most efficient ways of providing information to patients given the variety of patient information needs and learning styles?

4. In many REMS, patients receive counseling that may include a discussion of the benefits and risks of the drug as well as instructions on how to use the drug safely. In the majority of such REMS, prescribers are called upon to counsel patients, but other health care practitioners, including pharmacists and nurses, may also play a role in counseling patients. What are ways to improve current REMS approach to counseling patients? How should the timing and frequency of patient counseling be determined? Under what circumstances is it appropriate for prescribers to provide patient counseling in a REMS, when should other providers play a role in counseling patients in a REMS, and how can patient counseling in REMS be integrated into pharmacists' existing medication therapy management practices?

5. Many REMS with elements to assure safe use include prescriber-patient agreements. These agreements are used to document that an informed discussion of the drug's benefits and risks took place and that the patient understood the risks. Prescriber-patient agreements may also support patient counseling by providing information for prescribers to review with patients. Some REMS require that these agreements be signed by the prescriber and patient and submitted to the drug manufacturer. Are the information and agreements included in prescriber-patient agreements presented in a way that is easy for patients to understand and act upon? What, if anything, should be done to standardize, simplify, or streamline prescriber-patient agreement forms and the overall agreement process?

6. What else can be done to improve the effectiveness of existing patient-directed tools, to standardize them, to reduce their burden, and/or to better integrate them into the existing and evolving health care delivery system?

7. What tools and technologies not currently used in REMS could be incorporated into REMS to help counsel patients, to provide them with information on the risks of the drug, and to ensure that they use the drug safely? What evidence exists to support the effectiveness of these tools and technologies?

8. What projects could be carried out to standardize the provision of benefit-risk information to patients?

9. What methodologies exist or might be developed to assess the effectiveness of patient-directed REMS tools, the tools' burden on the health care delivery system, and the effect of these tools on patient access?

C. REMS Tools in Drug Dispensing Settings

Drug dispensing settings, such as prescribers' offices, hospitals, pharmacies (e.g., specialty, retail, and mail-order), integrated health care delivery systems, and infusion centers, often play a significant role in REMS. This is a challenging area to address because of the wide range of health care settings involved and because dispensers are frequently called upon to coordinate care across a range of health care settings and practitioners and to reinforce the tools that have been used by other health care practitioners. Specific dispensing settings may be required to obtain certification under a REMS, and, like prescribers, the health care practitioners who dispense a drug (authorized dispensers) may be required to complete training, counsel patients, and provide patients with educational materials, including Medication Guides. In addition, dispensers may be required to document that certain safe-use conditions are met before dispensing (e.g., by ordering/checking lab tests or completing a form or checklist).

Many REMS with elements to assure safe use require that specific health care settings be certified to be able to dispense the drug. To certify the health care setting, REMS typically require a representative of that health care setting to agree that the health care setting will meet all REMS requirements, including the completion of any necessary training.

1. Under what circumstances should individual practitioners within a health care setting (e.g., pharmacists, as opposed to pharmacies) be certified, instead of the health care setting? How could this effectively be accomplished while minimizing the burden on the health care system?

2. In most REMS that include dispenser certification, each dispensing site is certified individually. Under what circumstances would it be appropriate to use a single certification for a health care setting with multiple dispensing sites such as a pharmacy

chain, an integrated health care system, or a hospital system?

3. In what ways can the implementation of REMS tools in different dispensing settings be standardized, and under what circumstances might the implementation approach need to vary to accommodate the different types of dispensing settings that can be part of a REMS?

4. What obstacles have made it difficult for authorized dispensers to obtain drugs under existing REMS, and how can these be overcome?

5. How can REMS be made more compatible with existing systems for the procurement and distribution of drugs? How can REMS be integrated into any future electronic track and trace systems?

6. What else can be done to improve the effectiveness of existing REMS tools in drug dispensing settings, to standardize them, to reduce their burden, and/or to better integrate them into the existing and evolving health care delivery system?

7. What tools and technologies not currently used in REMS could be incorporated into REMS to help train and certify authorized dispensers, ensure that only certified dispensers can obtain the drug, and ensure that any safe-use conditions are met before a drug is dispensed? What evidence exists to support the effectiveness of these tools and technologies?

8. What projects could be carried out to integrate REMS tools into pharmacy systems?

9. What projects could be carried out to integrate REMS tools into other drug dispensing settings, such as hospitals, pharmacies, long-term care facilities, and integrated health care delivery systems?

10. What methodologies exist or might be developed to assess the effectiveness of REMS tools across the range of dispensing settings, the tools' burden on the health care delivery system, and the effect of these tools on patient access?

D. Approaches to Standardizing REMS Tools

Many stakeholders have asked FDA to standardize specific REMS tools like stakeholder enrollments, Web sites, and educational materials. Standardizing REMS tools will require ongoing collaboration among FDA, drug manufacturers, stakeholders, scientific experts, and others. To ensure that standardized tools are effective and minimally burdensome, they should be developed in an open and inclusive process that incorporates the feedback of all relevant stakeholders as well as the latest science and best practices from across the health care system. To ensure the continued success of these tools, they must be updated regularly as best practices evolve.

1. What opportunities and barriers exist for the development and implementation of standardized REMS tools? What are some ways that FDA can collaborate with third parties such as standards development organizations, industry groups, professional societies, and accreditation organizations to develop standardized REMS tools and ensure their adoption?

2. How might health information technologies such as electronic health records, pharmacy management systems and electronic prescribing systems be used to integrate REMS into existing health care settings? What role might health information technologies play in REMS in the future? How can these technologies be used to inform practitioners and patients about REMS, monitor patients, and document that any safe-use conditions are met? Could the integration of REMS into health information systems ever reduce or eliminate the need for other REMS tools, such as provider education?

3. Many stakeholders have suggested that a single Web portal should be established to act as a repository for standardized REMS tools and materials and to serve as a central information or reference source for REMS stakeholders. What barriers exist for the development of a single REMS Web portal? Who would be responsible for developing and maintaining the Web portal, and what role would FDA play?

E. Approaches To Assessing the Impact of REMS

Drug manufacturers are required to submit assessments of their REMS on a regular basis. To date, these assessments have tried to evaluate the effectiveness of the REMS by measuring the frequency of adverse outcomes of interest, the knowledge of stakeholders, and the compliance of stakeholders with certain REMS requirements. To accomplish this, drug manufacturers have relied on spontaneous adverse event reporting, knowledge surveys, and systems that track stakeholder completion of certain activities, such as enrollment and documentation of safe use conditions. To improve how REMS are assessed, FDA is considering additional areas for measurement and additional methods to measure the impact of REMS.

1. Should FDA routinely ask sponsors to assess the overall impact of their REMS on prescriber, dispenser, and patient burden, and/or access to the drug? If so, how could drug manufacturers assess the REMS impact on access and burden?

2. What methods might be used to separate the impact of a REMS program from that of other related risk management activities? Without having a control group, how should FDA interpret and act on REMS assessment information?

3. It is possible to interpret evidence of sustained REMS effectiveness to mean that the REMS should be maintained indefinitely, but such evidence may also suggest that safe use of the drug is now ingrained in the health care system and that the REMS can be modified or eliminated. What evidence could help FDA determine whether a drug would continue to be used safely if the REMS were modified or released?

IV. Attendance and Registration

The FDA Conference Center at the White Oak location is a federal facility with security procedures and limited seating. Attendance is free and will be on a first come, first served basis. Individuals who wish to present at the public meeting must register on or before July 10, 2013, through *http://remsmeeting.eventbrite.com* and provide complete contact information, including name, title, affiliation, address, email, and phone number. In section III of this document, FDA has included questions for comment. You should identify the questions you wish to address in your presentation, so that FDA can consider that in organizing the presentations. FDA will do its best to accommodate requests to speak, and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. An agenda will be available approximately 2 weeks before the meeting at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm351029.htm.*

If you need special accommodations because of disability, please contact Adam Kroetsch (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

A live Web cast of this meeting will be viewable at *https://collaboration.fda.gov/remsjuly2013/* on the day of the meeting. A video record of the meeting will be available at the same Web address for 1 year.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov*

or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. To ensure consideration, submit comment by (see **DATES**). 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.*

VI. 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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. 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.

Dated: May 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12124 Filed 5–21–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Science Board to the Food and Drug Administration; 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 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; and input into the Agency's research agenda; and 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 Monday, June 24, 2013, from approximately 1 p.m. to 3:45 p.m.

Location: Food and Drug Administration, White Oak Bldg. 31, Rm. 1503, section A, 10903 New Hampshire Ave., Silver Spring, MD 20993. This meeting will be held via teleconference (301–796–4100 or 866–901–3913; passcode: 665127) and via Adobe Connect (*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, White Oak Bldg. 32, Rm. 4286, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4627, email: *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 June 24, 2013, the Science Board will be provided draft final reports from the Center for Devices and Radiological Health Research Review subcommittee, and the Global Health subcommittee. A revised charge (initially proposed at the October 3, 2012, Science Board meeting) regarding a new subcommittee to evaluate the Agency's continuing work to address the challenges identified in the Science Board's 2007 ''Science and Mission at Risk'' Report will be presented.

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 Monday, June 17, 2013. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 1:45 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 Friday, June 7, 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 Monday, 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 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