

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications." The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the act) giving FDA the authority to require REMS. The draft guidance describes the format and content of a proposed risk evaluation and mitigation strategy, including REMS supporting documentation, the content of assessments and proposed modifications of approved REMS, what identifiers to use on REMS documents, and how to communicate with FDA about a REMS.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 30, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding questions for the Center for Drug Evaluation and Research:* Kathleen Frost, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4316, Silver Spring, MD 20993-0002, 301-796-2380.

*Regarding questions for the Center for Biologics Evaluation and Research:* Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications." On September 27, 2007, the President signed into law FDAAA (Public Law 110-85). Title IX, Subtitle A, section 901 of FDAAA created new section 505-1 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355-1). Section 505-1(a) of the act authorizes FDA to require persons who submit certain applications or hold certain approved applications<sup>1</sup> to submit a proposed REMS if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug and informs the holder of the application for the drug of the determination. Sections 505-1(c) through (f) describe the content of a required strategy. Section 505-1(g) describes assessments and modifications of an approved strategy.

The draft guidance provides information regarding FDA's current thinking on the format and content that should be used for submissions of proposed REMS, including a description of REMS supporting documentation. It also includes preliminary information on the content of assessments and proposed modifications of approved REMS, information on identifiers that should be included on the first page of REMS submissions, and information on whom to contact to communicate with FDA about a REMS.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the format and content of proposed REMS, REMS assessments, and proposed REMS modifications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative

<sup>1</sup> Section 505-1(b)(2) of the act (21 U.S.C. 355(p)(1)) provides that section 505-1 of the act applies to applications for prescription drugs approved under section 505(b) or (j) of the act and applications approved under section 351 of the Public Health Service Act (42 U.S.C. 262). See Section 505(p)(1).

approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in the guidance was approved under OMB control numbers 0910-0001 and 0910-0338.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.

Dated: September 25, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-23616 Filed 9-30-09; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting**

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Children's Study Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Children's Study Advisory Committee.

*Date:* October 21, 2009.

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

*Agenda:* The agenda will include a Report from the Director, NICHD, an update from the NCS Acting Director, discussions on recruitment strategies, the Vanguard Center protocol and interim outcome assessments. Additional information on the meeting logistics can be obtained on the conference Web site: <http://www.circlesolutions.com/ncs/ncsac/>.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Jessica Sapienza, Executive Secretary, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 3A01, Bethesda, MD 20892. (703) 902-1339. [ncs@circlesolutions.com](mailto:ncs@circlesolutions.com).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, drivers license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 24, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-23608 Filed 9-30-09; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

#### National Mammography Quality Assurance 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:* National Mammography Quality Assurance 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 2, 2009, from 9 a.m. to 5 p.m.

*Location:* Holiday Inn, Walker-Whetstone Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Normica Facey, Center for Devices and Radiological Health (White Oak, Bldg. 66, rm. 4652), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-5914, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512397. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting can not always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On November 2, 2009, the committee will discuss guidance documents issued since the last meeting. The committee will also receive updates on: Interventional mammography accreditation programs, recently approved alternative standards, facility inspection findings, the status of current inspection followup actions, and the radiological health program.

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 may be made to the contact person on or before October 29, 2009. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. Those desiring

to make 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 23, 2009. 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 26, 2009.

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, Conference Management Staff, 301-796-5966, 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 25, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-23621 Filed 9-30-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

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 meeting.

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