

Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meets specified standards and address the specified research questions. To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. The statutory authority for this policy is section 1862(a)(1)(E) of the Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management. *Form Number:* CMS-10152 (OCN: 0938-0968); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 25000; *Total Annual Responses:* 25000; *Total Annual Hours:* 2,084 hours. (For policy questions regarding this collection contact Stuart Caplan at 410-786-8564. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* Revision; *Title of Information Collection:* Recognized Accrediting Entities Data Collection; *Use:* The final rule that was released on July 20, 2012 (77 FR 42658) establishes a process for recognizing accrediting entities for the purposes of implementing section 1311(c)(1)(D)(i) of the Affordable Care Act. In order for a health plan to be certified as a QHP and operate in an Exchange, it must be accredited by an accrediting entity that has been recognized by the Secretary of Health and Human Services. The final rule establishes the first phase of a two-phased process for recognition of accrediting entities. In phase one, the National Committee for Quality Assurance (NCQA) and URAC were recognized as accrediting entities for the purposes of fulfilling the accreditation requirement as part of qualified health plan certification. In a subsequent final rule, released February 22, 2013, we amended the first phase of this process to allow additional accrediting entities to apply to be recognized. The assessment used to assess these additional accrediting entities will be the same as the assessment underlying the recognition of NCQA and URAC. This information collection is necessary to ensure that the recognized accrediting entities meet the proposed conditions. 45 CFR 156.275(c) requires that the accrediting entities provide accreditation survey data elements, including accreditation status,

accreditation score, accreditation expiration date, clinical quality measure results and adult and child CAHPS measure survey results to the Exchanges once these data are released by the issuers. Further, accrediting entities applying to be recognized must provide to HHS the accreditation standards and requirements, processes, and measure specifications for performance measures and, once recognized, any proposed changes or updates to these standards, and requirements, processes and measure specifications with 60-day notice prior to public notification. This collection, which is approved under OCN: 0938-1176), is necessary in order for Exchanges to verify that the QHPs being offered in their Exchange meet the accreditation requirement and are high quality plans.

The 60-day **Federal Register** notice published on November 23, 2012 (77 FR 70163). We received two comments. The comments concerned issuer burden associated with the data collection and the content of the data submission. These comments were addressed in full in the Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule. Generally, we noted that this data collection pertained to the submission of data from accrediting entities seeking to be recognized and accrediting entities already recognized, rather than issuers. Comments related to the content of the data submission were deemed out of scope. *Form Number:* CMS-10449; *Frequency:* Monthly, Occasionally; *Affected Public:* Private sector, Not-for-profit institutions; *Number of Respondents:* 4; *Number of Responses:* 60; *Total Annual Hours:* 3,544. (For policy questions regarding this collection contact Rebecca Zimmermann at (301) 492-4396. For all other issues, call (410) 786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on **April 15, 2013**: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax

Number: (202) 395-6974, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: March 8, 2013.

**Martique Jones**,  
Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013-05802 Filed 3-13-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

#### Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the 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 Committees:* Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee.

*General Function of the Committees:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 18, 2013, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 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:* Kalyani Bhatt, 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: [ACRHD@fda.hhs.gov](mailto:ACRHD@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 link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss the efficacy and safety of new drug application (NDA) 22219, AVEED (testosterone undecanoate) intramuscular injection, submitted by Endo Pharmaceutical Solutions, Inc., for the proposed indication of replacement therapy in adult males for conditions associated with a deficiency or absence of testosterone. The safety discussion will focus on postmarketing reports of oil embolism in the lungs and potential anaphylactic reactions. In addition to AVEED, other approved testosterone injectable products will be referenced, especially in regard to oil embolism and potential anaphylactic reactions reported for those products.

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 April 4, 2013. 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 March 27, 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 March 28, 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 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: <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: March 8, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-05861 Filed 3-13-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

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 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/or contract proposals 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 or the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Cancer Institute Special Emphasis Panel, NCI Provocative Questions.

**Date:** March 28, 2013.

**Time:** 7:30 a.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852.

**Contact Person:** Peter J. Wirth, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8131, Bethesda, MD 20892-8328 301-496-7565 [pw2q@nih.gov](mailto:pw2q@nih.gov).

**Name of Committee:** National Cancer Institute Special Emphasis Panel, Nanotechnology RNA Therapeutics.

**Date:** April 18-19, 2013.

**Time:** 9:00 a.m. to 5:00 p.m.

**Agenda:** To review and evaluate contract proposals.

**Place:** Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Thomas M. Vollberg, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7142, Bethesda, MD 20892, 301-594-9582, [vollbert@mail.nih.gov](mailto:vollbert@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 8, 2013.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-05847 Filed 3-13-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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 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.