

Medicare conditions for participation for psychiatric hospitals.

### III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for psychiatric hospitals. This application was determined to be complete on September 3, 2010. Under section 1865(a)(2) of the Act and § 488.8 (Federal review of accrediting organizations), our review and evaluation of the Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of the Joint Commission's standards for a psychiatric hospital as compared with CMS' psychiatric hospital conditions of participation.
- The Joint Commission's survey process to determine the following:
  - + The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
  - + The comparability of the Joint Commission's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  - + The Joint Commission's processes and procedures for monitoring psychiatric hospitals found out of compliance with the Joint Commission's program requirements. These monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).
  - + The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
  - + The Joint Commission's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.
  - + The adequacy of the Joint Commission's staff and other resources, and its financial viability.
  - + The Joint Commission's capacity to adequately fund required surveys.
  - + The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.
  - + The Joint Commission's agreement to provide us with a copy of the most current accreditation survey together with any other information related to

the survey as we may require (including corrective action plans).

### IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

### V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

### VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or Tribal governments.

**Authority:** Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 14, 2010.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

### Oncologic Drugs 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:* Oncologic Drugs 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 December 1, 2010, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, Bldg 31, the Great Room, White Oak Conference Center (rm. 1503), 10903 New Hampshire Ave., 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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings".

*Contact Person:* Nicole Vesely, 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, e-mail: [Nicole.vesely@fda.hhs.gov](mailto:Nicole.vesely@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 301-451-2542. 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 cannot 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 December 1, 2010, the committee will discuss supplemental new drug applications (sNDAs) 021-319/S-024, trade name AVODART (dutasteride) Soft Gelatin Capsules,

manufactured by SmithKline Beecham Corp. d/b/a (doing business as) GlaxoSmithKline and 020-180/S-034, trade name PROSCAR (finasteride) Tablets, manufactured by Merck & Co., Inc. The proposed indication (use) for AVODART (dutasteride) is for reduction in the risk of prostate cancer in men at increased risk of developing the disease. The population at increased risk of prostate cancer includes men with an elevated serum prostate-specific antigen (PSA) or men otherwise determined to be at increased risk based on other associated risk factors such as age, race, and family history. There is no proposed expansion of the indication for PROSCAR (finasteride); however, in light of the Prostate Cancer Prevention Trial (PCPT) which demonstrated a statistically significant reduction in the 7-year period prevalence of prostate cancer with finasteride (PROSCAR) treatment, and which reported an imbalance in high Gleason grade prostate cancers (indicating more aggressive cancers) in the finasteride treatment arm vs. placebo, the efficacy and safety of both products for use in prostate cancer risk reduction will be examined.

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 November 16, 2010. Oral presentations from the public will be scheduled between approximately 2:30 p.m. to 3:30 p.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 November 8, 2010. 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 November 9, 2010.

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 Nicole Vesely 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: October 13, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-26651 Filed 10-21-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Basic Behavioral and Social Science Opportunity Network (OppNet)

**ACTION:** Notice.

**SUMMARY:** A two-day meeting highlighting OppNet's activities and future goals is scheduled for Thursday, October 28, and Friday, October 29, 2010, at the Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW., Washington DC 20001. This is the first public meeting to promote and publicize the Basic Behavioral and Social Science Opportunity Network (OppNet) initiative. Attendance is limited to prior registration via <http://www.regonline.com/oppnet>.

**Background:** The Basic Behavioral and Social Science Opportunity Network (OppNet) is a trans-NIH initiative to expand the agency's funding of basic behavioral and social sciences research (b-BSSR). OppNet prioritizes activities and initiatives that focus on basic mechanisms of behavior

and social processes that are relevant to the missions and public health challenges of multiple NIH Institutes, Centers, and Offices (ICOs) and that build upon existing NIH investments without replicating them. <http://www.oppnet.nih.gov>.

**Participating:** The meeting will take place on October 28, from 9 a.m. to 4:30 p.m., and October 29, from 8:30 a.m. to 2:30 p.m., at the Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW., Washington DC 20001.

**FOR FURTHER INFORMATION CONTACT:** To register, visit the registration Web site at <http://regonline.com/oppnet>, call William Elwood at 301-402-0116, or e-mail [elwoodwi@od.nih.gov](mailto:elwoodwi@od.nih.gov).

Dated: October 15, 2010.

**Lawrence A. Tabak,**

*Principal Deputy Director, National Institutes of Health.*

[FR Doc. 2010-26709 Filed 10-21-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; 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.

**Name of Committee:** National Institute of General Medical Sciences Special Emphasis Panel; Review of Minority Biomedical Research Neuro Grant Applications.

**Date:** December 6, 2010.

**Time:** 8:30 a.m. to 5 p.m.

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

**Place:** Hyatt Regency-Bethesda, 7400 Wisconsin Avenue, One Bethesda Metro Center, Bethesda, MD 20814.

**Contact Person:** John J. Laffan, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18J, Bethesda, MD 20892, 301-594-2773, [laffanjo@mail.nih.gov](mailto:laffanjo@mail.nih.gov).