

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.

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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.

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]

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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.