Contact Person: Teresa Watkins, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane,rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *teresa.watkins@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512545. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the efficacy supplement to new drug application (NDA) 21–077 for the approved product Advair Diskus 500/50 (fluticasone propionate/salmeterol inhalation powder) by GlaxoSmithKline, for the proposed indication of increased survival and reduced exacerbations in patients with chronic obstructive pulmonary disease (COPD).

FDA intends to make background material available to the public no later than 1 business day 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/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and 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 April 11, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 April 3, 2007. 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 April 4, 2007.

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 Teresa Watkins at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 14, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–5194 Filed 3–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

The National Cancer Advisory Board's Breast Cancer Prevention Trail P–4 Working Group will meet to discuss the P–4 trial which is designed to perform a 10-year study in risk-eligible, postmenopausal women to determine whether letrozole is more effective than raloxifene in reducing the incidence of invasive breast cancer in this otherwise healthy population. The meeting will be closed to the public.

The thoughts and input from this meeting will be summarized in a report that will be presented to the National Cancer Advisory Board in open session at an upcoming meeting.

Name of Work Group: National Cancer Advisory Board, Breast Cancer Prevention Trial P–4 Working Group.

Closed: March 23, 2007, 8:30 a.m. to 4:30 p.m.

Agenda: The purpose of the Work Group will be to ensure that funds are invested optimally to achieve outcomes that utilize the best of clinical and molecular sciences to answer key scientific questions, produce extremely valuable data sets for the community, and, in this instance, provide maximal benefit to breast cancer patients.

Place: Hyatt Regency Building, One Metro Center, Bethesda, MD 20814.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Advisory Board, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

SUPPLEMENTARY INFORMATION:

Background

Over the past several years the National Cancer Institute has performed a series of important prevention clinical trials to study the effects) of tamoxifen, raloxifene (Selective Estrogen Receptor Modulators—SERMS) and, subsequently, aromatase inhibitors such as letrozole on reducing the incidence of invasive breast cancer in defined populations of postmenopausal women. As follow-on to this series of breast cancer prevention trials, a new trial in the sequence, the P–4 trial, has been proposed and peer-reviewed. The P–4 trial is designed to perform a 10-year study in risk-eligible, postmenopausal women to determine whether letrozole is more effective than raloxifene in reducing the incidence of invasive breast cancer in this otherwise healthy population. The trial will accrue 12,800 patients over 4 years. The primary endpoint for this trial will be the first occurrence of invasive breast cancer. Secondary endpoints will include DCIS; LCIS; ischemic heart disease; fracture of the wrist, hip, and spine; DVTs; PEs; TIAs and stroke; death; other invasive cancers; and quality of life.

P–4 trial is a significant financial commitment on the part of the National Cancer Institute and of the cancer research community. Additionally, the outcome of this trail will require more than 10 years of study. Given the magnitude of this investment, the rapid acceleration of progress in molecular genetics and molecular biology, and the disparate range of views on the trial, the National Cancer Advisory Board is convening a group of experts to provide feedback to the National Cancer Advisory Board.

Any interested person may file written comments with the work group 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.

(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 16, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1408 Filed 3–21–07; 8:45 am]

BILLING CODE 4140–01–M