SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at http://www.fda.gov/Drugs/Guidance ComplianceRegulatoryInformation/Guidances/default.htm. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for fluticasone propionate; salmeterol xinafoate.

Advair Diskus (fluticasone propionate; salmeterol xinafoate), new drug application 021077, was initially approved by FDA in August 2000. There are no approved ANDAs for this product. FDA is now issuing a draft guidance for industry on BE recommendations for generic fluticasone propionate; salmeterol xinafoate (Draft Fluticasone Propionate; Salmeterol Xinafoate BE Recommendations).

In December 2009, GlaxoSmithKline (GSK), manufacturer of the reference listed drug Advair Diskus, submitted a citizen petition requesting that FDA withhold approval of any ANDA or 505(b)(2) application for generic oral inhalation products containing fluticasone propionate and/or salmeterol xinafoate unless certain conditions were satisfied, including conditions related to demonstrating BE (Docket No. FDA–2009–P–0597). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the Draft Fluticasone Propionate; Salmeterol Xinafoate BE Recommendations before responding to GSK’s citizen petition.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the design of BE studies to support ANDAs for fluticasone propionate; salmeterol xinafoate. 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 approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/Guidance ComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.


Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps (NHSC).

DATES: Dates and Times: September 26, 2013, 2:00 p.m.–3:30 p.m. (EST).

Place: The meeting will be via audio conference call.

Status: The meeting will be open to the public.

Agenda: The Council is holding a meeting via conference call to discuss the National Health Service Corps role in the Affordable Care Act. The public can join the meeting via audio conference call on the date and time specified above using the following information: Dial-in number: 1–860–857–5081; Passcode: 1060359. There will be an opportunity for the public to comment towards the end of the call.

FOR FURTHER INFORMATION CONTACT: Njei Jones, Bureau of Clinician Recruitment and Service, Health Resources and Services Administration, Parklawn Building, Room 13–64, 5600 Fishers Lane, Rockville, Maryland 20857; email: NJones@hrsa.gov; telephone: 301–443–2541.


Bahar Niakan, Director, Division of Policy and Information Coordination.
FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed application, contact: Sarah Kobrin, Division of Cancer Control and Population Sciences, 9609 Medical Center Dr., MSC 9761, Rockville, MD 20852, or call non-toll-free number 240–276–6931 or Email your request, including your address to: kobrins@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Awareness and Beliefs about Cancer Survey, 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The objective of the study is to gather data about American adults’ awareness and beliefs about cancer. The ultimate goal is to determine how individuals’ perceptions of cancer may influence their decisions to report signs and symptoms to health care providers, perhaps affecting the disease stage of diagnosis and the effectiveness of treatment. Data will be collected from approximately 2,000 adults aged 50 years or older across the United States will be recruited for the NCI Awareness and Beliefs about Cancer survey over a one-year period.

OMB approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,334.

### ESTIMATED ANNUALIZED BURDEN HOURS

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<th>Form name</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total annual burden hour</th>
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Vivian Horovitch-Kelley, NCI Project Clearance Liaison, National Institutes of Health.

Bill: [FR Doc. 2013–21977 Filed 9–9–13; 8:45 am]

BILLING CODE 4140–01–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Library of Medicine; 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 materials, 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 Library of Medicine Special Emphasis Panel; Conflicts R01/K22.

**Date:** October 30, 2013.

**Time:** 12:00 p.m. to 2:00 p.m.

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

**Place:** National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20817 (Telephone Conference Call).

**Contact Person:** Zoe E. Huang, M.D., Scientific Review Officer, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–594–4937, huangz@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHSS)


Michelle Trout, Program Analyst, Office of the Federal Advisory Committee Policy.

Bill: [FR Doc. 2013–21948 Filed 9–9–13; 8:45 am]

BILLING CODE 4140–01–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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 a meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Drug Abuse, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** Board of Scientific Counselors, NIDA.

**Date:** October 22, 2013.

**Closed:** 8:00 a.m. to 6:00 p.m.

**Agenda:** To review and evaluate personal qualifications and performance, and competence of individual investigators.

**Place:** Intramural Research Program, National Institute on Drug Abuse, NIH, Johns Hopkins Bayview Campus, Baltimore, MD 21223.

**Contact Person:** Joshua Kysiak, Program Specialist, Biomedical Research Center, Intramural Research Program, National Institute on Drug Abuse, NIH, DHHS, 251 Bayview Boulevard, Baltimore, MD 21224, 443–740–2465, kysiakjo@nida.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHSS)


Michelle Trout, Program Analyst, Office of Federal Advisory Committee Policy.

Bill: [FR Doc. 2013–21947 Filed 9–9–13; 8:45 am]

BILLING CODE 4140–01–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; 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