

## 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/GuidanceComplianceRegulatoryInformation/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 FDA is now issuing a draft guidance for industry on BE recommendations for generic fluticasone propionate; salmeterol xinafoate (Draft Fluticasone Propionate; Salmeterol Xinafoate BE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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for fluticasone propionate; salmeterol xinafoate.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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 3, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## 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: 1-800-857-5081; Passcode: 1060359. There will be an opportunity for the public to comment towards the end of the call.

**FOR FURTHER INFORMATION CONTACT:**

Njeri 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](mailto:NJones@hrsa.gov); telephone: 301-443-2541.

Dated: September 4, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## National Institutes of Health

## Submission for OMB Review; 30-Day Comment Request: Awareness and Beliefs About Cancer Survey, National Cancer Institute (NCI)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 19, 2013, Vol. 78, page 36788 and allowed 60-days for public comment. One public comment was received on June 21, 2013 requesting the data collection plans and instruments. This information was sent to the individual on June 24, 2013. Another comment was received on August 14, 2013. Data collection plans and instruments were sent to the requester on August 14, 2013. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.