

“Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND.” FDA’s primary objectives in requiring the submission of and reviewing an IND are to assure the safety and rights of subjects and, in Phases 2 and 3 of an investigation, to help assure the quality of the scientific evaluation of the drug is adequate to permit an evaluation of the drug’s effectiveness and safety.

FDA receives frequent inquiries from external constituents, in particular the academic research community (e.g., clinical investigators, IRBs) and the pharmaceutical industry, about whether various types of human research studies can be conducted without an IND. These inquiries have addressed a range of issues concerning application of the IND requirements in 21 CFR part 312, including clinical investigations using marketed drugs, bioequivalence and bioavailability studies, studies using radiolabeled or cold isotopes, studies using foods or dietary supplements, studies using endogenous compounds, pathogenesis studies using modified organisms, studies using wild-type organisms in challenge models, and studies that do not have a commercial purpose. Because of the volume and nature of inquiries, this guidance is intended to assist clinical investigators, sponsors, sponsor-investigators, and IRBs in determining whether an IND should be submitted for their planned research.

This guidance provides an overview of the general requirements for determining whether a study involving human subjects requires submission of an IND, describes the types of studies that involve drugs but are exempt by regulation from the IND requirements, and addresses a range of issues that commonly arise in inquiries to FDA concerning the application of the IND requirements. This guidance also provides a process for seeking advice from FDA concerning the application of the IND regulations to a planned clinical investigation.

In the **Federal Register** of October 14, 2010 (75 FR 63189), FDA announced the availability of a draft version of this guidance. The October 2010 guidance gave interested persons an opportunity to submit comments through January 12, 2011. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. Most of the comments related to requests to provide additional clarifications on specific recommendations in the draft guidance. As a result of the public comment, certain sections of the

guidance have been reworded to improve clarity. In addition, information has been added to explain the application of the IND regulations to studies of ingredients or products marketed as cosmetics, studies intended to evaluate conventional foods, and studies intended to support a health claim.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on determining whether human research studies can be conducted without an IND. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm>, or <http://www.regulations.gov>.

Dated: September 2, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2007–D–0369]

#### **Draft Guidance for Industry on Bioequivalence Recommendations for Fluticasone Propionate; Salmeterol Xinafoate; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Fluticasone Propionate; Salmeterol Xinafoate.” The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for fluticasone propionate; salmeterol xinafoate.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 12, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Bhawana Saluja, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8465.

## 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.*

[FR Doc. 2013-21892 Filed 9-9-13; 8:45 am]

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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.*

[FR Doc. 2013-21966 Filed 9-9-13; 8:45 am]

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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.