

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

GDUFA (Pub. L. 112-144, Title III) was signed into law by the President on July 9, 2012. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program.

GDUFA establishes fees for abbreviated new drug applications (ANDAs), prior approval supplements (PASs) to ANDAs, and drug master files (DMFs), annual facility fees, and a one-time fee for original ANDAs pending with FDA on October 1, 2012 (backlog fees). Fees are incurred for ANDAs and PASs submitted on or after October 1, 2012. An application fee is also incurred the first time a DMF is referenced in an ANDA or PAS submitted on or after October 1, 2012. FDA previously announced GDUFA fees for fiscal year 2013 in the **Federal Register**. ANDA, PAS, and DMF fees were published on October 25, 2012 (77 FR 65198); the backlog fee was published on October 25, 2012 (77 FR 65199); and facility fees were published on January 17, 2013 (78 FR 3900). GDUFA fees for fiscal year 2014 were announced in the **Federal Register** of August 2, 2013 (78 FR 46977).

On August 27, 2012, FDA announced the availability of a draft guidance for industry entitled "Generic Drug User Fee Amendments of 2012: Questions and Answers" (77 FR 51814). The comment period on the draft guidance closed on October 26, 2012. In response to comments received in the docket and to address additional questions that have arisen since the launch of the GDUFA program, FDA has revised the draft guidance and is issuing it again in draft to solicit public comment. Revision 1 clarifies some of the questions and answers in the first version and adds several new questions and answers. The questions and answers address four key categories: Fees; self-identification of facilities, sites, and organizations; review of generic drug submissions; and inspections and compliance.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when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 "Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1)." 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>.

Dated: September 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-D-0503]

Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards on Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for clinical investigators, sponsors, and institutional review boards (IRBs) entitled "Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND." The guidance is intended to assist clinical investigators,

sponsors, sponsor-investigators, and IRBs in determining whether human research studies must be conducted under an IND. The guidance describes the basic criteria for determining when an IND is required, describes specific situations in which an IND is not required, and addresses a range of issues that, in FDA's experience, have been the source of confusion or misperceptions about the application of the IND regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448; or Outreach and Information Center (HFS-009), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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:

Peter Taschenberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2211, Silver Spring, MD 20993-0002, 301-796-2500, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210, or David Hattan, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1293.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a guidance for clinical investigators, sponsors, and IRBs entitled

“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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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.