



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances for Salmeterol Xinafoate and Fluticasone Propionate; Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of three draft guidances for industry on generic salmeterol xinafoate inhalation powder, fluticasone propionate inhalation aerosol, and fluticasone propionate inhalation powder, entitled “Draft Guidance on Salmeterol Xinafoate” and “Draft Guidance on Fluticasone Propionate.” The guidances, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for salmeterol xinafoate inhalation powder, fluticasone propionate inhalation aerosol, and fluticasone propionate inhalation powder.

DATES: Submit either electronic or written comments on the draft guidances by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2007-D-0369 for "Draft Guidance on Salmeterol Xinafoate" or "Draft Guidance on Fluticasone Propionate." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, 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 documents.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

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 guidances available to the public on FDA’s Web site at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of draft product-specific guidances for generic salmeterol xinafoate inhalation powder, fluticasone propionate inhalation aerosol, and fluticasone propionate inhalation powder.

FDA initially approved new drug application (NDA) 020692 for SEREVENT DISKUS (salmeterol xinafoate inhalation powder) in September 1997. We are now issuing a draft guidance for industry on, among other things, BE recommendations for generic salmeterol xinafoate inhalation powder (“Draft Guidance on Salmeterol Xinafoate”).

FDA initially approved NDA 021433 for FLOVENT HFA (fluticasone propionate inhalation aerosol) in May 2004 and NDA 020833 for FLOVENT DISKUS 100 (fluticasone

propionate inhalation powder) in September 2000. We are now also issuing two draft guidances for industry on, among other things, BE recommendations for generic fluticasone propionate inhalation aerosol and fluticasone propionate inhalation powder (both entitled “Draft Guidance on Fluticasone Propionate”).

In December 2009, GlaxoSmithKline (GSK), manufacturer of the reference listed drugs SEREVENT DISKUS, FLOVENT HFA, and FLOVENT DISKUS 100, submitted a citizen petition requesting that FDA withhold approval of any ANDA or 505(b)(2) application for generic oral inhalation products containing salmeterol xinafoate and/or fluticasone propionate 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 guidances entitled, “Draft Guidance on Salmeterol Xinafoate” or “Draft Guidance on Fluticasone Propionate,” before responding to GSK’s citizen petition.

The draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the design of BE studies to support ANDAs for salmeterol xinafoate inhalation powder, fluticasone propionate inhalation aerosol, and fluticasone propionate inhalation powder. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. These guidances are not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidances at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 16, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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