Dated: November 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28438 Filed 11–26–13; 8:45 am]

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Draft Guidance for Industry on Bioequivalence Recommendations for Fluticasone Propionate; Salmeterol Xinafoate; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability entitled ''Draft Guidance for Industry on Bioequivalence Recommendations for Fluticasone Propionate; Salmeterol Xinafoate'', published in the **Federal Register** of September 10, 2013 (78 FR 55263). In that notice, FDA requested public comment on the draft guidance. FDA is reopening the comment period due to the inability of some commenters to submit comments through the *www.regulations.gov* Web site from November 4, 2013, through November 13, 2013, due to technical difficulties.

DATES: Submit either electronic or written comments to the docket by December 11, 2013.

ADDRESSES: Submit electronic comments 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–643), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8465.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 10, 2013 (78 FR 55263), FDA announced the notice of availability for the draft guidance entitled ''Draft Guidance for Industry on Bioequivalence Recommendations for Fluticasone Propionate; Salmeterol Xinafoate.'' Interested persons were given until November 12, 2013, to provide comments. The Agency is reopening the comment period until December 11, 2013 to allow interested persons additional time to submit comments.

II. Request for Comments

Following publication of the September 10, 2013, notice of availability, there were technical difficulties with the *www.regulations.gov* Web site from November 4, 2013, through November 13, 2013, which would have prevented comments from being submitted.

III. How To Submit 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.*

Dated: November 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28394 Filed 11–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0880]

Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1); Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability entitled ''Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1)'', published in the **Federal Register** of September 10, 2013 (78 FR 55261). In that notice, FDA requested public comment on the draft guidance. FDA is reopening the comment period due to the inability of some commenters to submit comments through the *www.regulations.gov* Web site from November 4, 2013, through November 13, 2013, due to technical difficulties.

DATES: Submit either electronic or written comments to the docket by December 11, 2013.

ADDRESSES: Submit electronic comments 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: Jaewon Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., rm. 4145, Silver Spring, MD 20993–0002, 301–796–6707, email: *askGDUFA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 10, 2013 (78 FR 55261), FDA announced the notice of availability for the draft guidance entitled ''Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1).'' Interested persons were given until November 12, 2013, to provide comments. The Agency is reopening the comment period until December 11, 2013 to allow interested persons additional time to submit comments.

II. Requests for Comments

Following publication of the September 10, 2013, notice of availability, there were technical difficulties with the *www.regulations.gov* Web site from November 4, 2013, through November 13, 2013, which would have prevented comments from being submitted.

III. How To Submit 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.*

Dated: November 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28392 Filed 11–26–13; 8:45 am]

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