SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Immunogenicity-Related Considerations for the Approval of Low Molecular Weight Heparin for NDAs and ANDAs.'' This draft guidance provides recommendations to applicants for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) regarding impurities and their potential effect on immunogenicity for LMWH. The draft guidance also includes recommendations on meeting the requirement for active ingredient sameness for ANDAs. A demonstration of active ingredient sameness helps to address immunogenicity in the context of ANDAs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on immunogenicity-related considerations for low molecular weight heparin for NDAs and ANDAs. 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. The Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information that is 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 collection of information in 21 CFR part 314 has been approved under OMB control number 0910–0001.

III. 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.*

IV. 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: April 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07896 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1445]

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to May 7, 2014, the comment period for the notice that appeared in the **Federal Register** of January 7, 2014 (79 FR 830). In the notice, FDA requested comments on a draft guidance document entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' Submit either electronic or written comments by May 7, 2014.

ADDRESSES: 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. 1601, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Patricia Bernhardt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5654, Silver Spring, MD 20993–0002.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 7, 2014 (79 FR 830), FDA published a notice announcing the availability of the draft guidance entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' Interested persons were invited to submit comments by April 7, 2014. At this time the Agency is extending the comment period until May 7, 2014, to continue to receive public comments. Comments submitted to the docket will assist in identifying issues to be addressed in the finalized guidance document.

II. Request for 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: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07898 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1446]

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to May 7, 2014, the comment period for the notice that appeared in the **Federal Register** of January 7, 2014 (79 FR 829). In the notice, FDA requested comments on the draft guidance document entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance entitled ''Self-Monitoring Blood Glucose Test

Systems for Over-the-Counter Use.'' Submit either electronic or written comments by May 7, 2014.

ADDRESSES: 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. 1601, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Patricia Bernhardt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5654, Silver Spring, MD 20993–0002, 301–796–6136.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 7, 2014 (79 FR 829), FDA published a notice announcing the availability of the draft guidance entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' Interested persons were invited to submit comments by April 7, 2014. At this time the Agency is extending the comment period until May 7, 2014, to continue to receive public comments. Comments submitted to the docket will assist in identifying issues to be addressed in the finalized guidance document.

II. Request for 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: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07899 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0313]

Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development; 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, researchers, patient groups, and FDA staff entitled ''Meetings With the Office of Orphan Products Development.'' This draft guidance provides recommendations to industry, researchers, patient groups, and other stakeholders (collectively referred to as ''stakeholders'') interested in requesting a meeting with FDA's Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device (HUD) designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. This draft guidance document is intended to assist these groups with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD.

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 comment 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 or proposed collection of information by June 9, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on 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. Identify comments with the docket number found in brackets in the heading of this document. OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: James Bona, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993, 301–796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, researchers, patient groups, and FDA staff entitled ''Meetings With the Office of Orphan Products Development.'' Each year, OOPD staff participates in meetings with stakeholders who seek guidance or clarification relating to orphan drug or HUD designation requests, OOPD grant programs, or other rare disease issues. These meetings can be ''informal'' or ''formal'' and help build a common understanding on FDA's thoughts on orphan products, which include drugs, biological products, devices, or medical foods. These meetings may represent critical points in the orphan product development process and may even have an impact on the eventual availability of products for patients with rare diseases and conditions. It is important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate. This guidance is intended to provide consistent procedures to promote well managed meetings between OOPD and stakeholders.

Topics addressed in this guidance include: (1) Clarification of what constitutes an ''informal'' or ''formal'' meeting, (2) program areas within OOPD that may be affected by this draft guidance, (3) procedures for requesting and scheduling meetings with OOPD, (4) description of what constitutes a meeting package, and (5) procedures for the conduct and documentation of meetings with OOPD.

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 meetings with OOPD. It does not create or confer any rights for or on any