of Honey and Honey Products.'' FDA developed this draft guidance to advise firms on the proper labeling of honey and honey products to help ensure that honey and honey products are not adulterated or misbranded.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 9, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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: April Kates, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Proper Labeling of Honey and Honey Products'' dated February 2014. On March 8, 2006, the American Beekeeping Federation and several other honey-related associations submitted a citizen petition requesting that FDA adopt a U.S. standard of identity for honey based on the 2001 Revised Codex Alimentarius Commission's Standard for Honey. The petitioners asserted that a U.S. standard of identity for honey would achieve the following goals: (1) Clarify what the term ''honey'' means with respect to the food's composition and therefore promote honesty and fair dealing in the interest of consumers; (2) combat economic adulteration of honey by aiding enforcement and industry compliance; and (3) promote honesty and fair dealing within the food trade in general, where pure honey is used as an ingredient in other food. In a letter dated October 5, 2011, we denied the petition because the petition did not provide reasonable grounds for FDA to adopt the Codex standard for honey. We also concluded that the petitioners' goals can be achieved by FDA's existing authorities and that a standard of identity for honey would not promote honesty and fair dealing in the interest of consumers.

To address the labeling issues relevant to the petition, we developed this draft guidance to advise the regulated food industry on the proper labeling of honey and honey products to help ensure that honey and honey products are not adulterated or misbranded under sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342 and 343, respectively).

We are issuing this draft guidance document consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on the labeling of honey and honey products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 101.4, 101.22, and 102 have been approved under OMB control number 0910–0381.

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 draft guidance document at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*.

Dated: April 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07925 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–0310]

Draft Guidance for Industry on Immunogenicity-Related Considerations for the Approval of Low Molecular Weight Heparin for New Drug Applications and Abbreviated New Drug Applications; 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 ''Immunogenicity-Related Considerations for the Approval of Low Molecular Weight Heparin for NDAs and ANDAs.'' This guidance discusses how applicants for low molecular weight heparin (LMWH) products should provide information on impurities and the potential impact on immunogenicity.

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 by June 9, 2014.

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: Daniela Verthelyi, Center for Drug Evaluation and Research (HFD–122), Food and Drug Administration, 9000 Rockville Pike, N29A, Rm. 3B19, Bethesda, MD 20892, 301–827–1702.

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