CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*.

To receive ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1756 to identify the guidance you are requesting.

IV. 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This draft guidance refers to previously approved collections of information found in FDA regulations.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 Part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR Part 820 have been approved under OMB control number 0910–0073.

V. 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: January 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00022 Filed 1–6–14; 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Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' This draft guidance document describes studies and criteria FDA recommends for blood glucose monitoring test systems (BGMSs) which are for prescription point-of-care use. When finalized, FDA intends for this document to guide manufacturers in conducting appropriate performance studies and preparing premarket notifications for these device types. This draft guidance is not final nor is it in effect at this time.

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 April 7, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use '' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the 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. 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

This draft guidance document describes studies and criteria FDA recommends for blood glucose monitoring test systems (BGMSs) which are for prescription point-of-care use. When finalized, FDA intends for this document to guide manufacturers in conducting appropriate performance studies and preparing premarket notifications for these device types. Portable blood glucose monitoring test systems (glucose meters) that measure blood glucose concentrations are widely used in hospitals as well as in a variety of other clinical settings including both acute and chronic care facilities, general hospital wards and intensive care units, physicians' offices, assisted living facilities and nursing homes.

Historically, FDA has not recommended different types of information in premarket submissions (510(k)s) for blood glucose meters used by medical professionals as compared to over-the-counter self-monitoring devices intended for use by lay users. In recent years, however, concerns have been raised including infection control issues related to point-of-care glucose meters. According to the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC), blood glucose monitoring devices can transmit bloodborne pathogens if these devices are contaminated with blood specimens and are shared between users without effective cleaning, disinfecting and appropriate infection control measures. Because BGMS devices, which are used in professional healthcare settings, are more likely to be used on multiple patients, this type of use requires certain design features and cleaning capability to prevent the spread of blood-borne pathogens.

In addition, concerns have been raised citing the inability of currently cleared BGMS devices to perform effectively in professional healthcare settings because the device's safety and effectiveness have not been evaluated for some of the intended use populations. Patients in these settings are often fundamentally different than lay users using these devices at home. Patients in professional healthcare settings can be acutely ill and medically fragile and are more likely to present physiological and pathological factors

that could interfere with glucose measurements as compared to the lay population. Errors in BGMS device accuracy can lead to incorrect insulin dosing, which, when combined with other factors, can lead to increased episodes of hypoglycemia. For hospitalized patients who may be seriously ill, any inaccuracies in the meters would further increase the risk to these patients. Previously, most blood glucose monitoring devices, even those intended to be used by healthcare professionals, were submitted to FDA with claims for OTC use. Thus, they were evaluated for use in the lay population, and the specific issues that occur in the professional healthcare setting were never addressed, the performance of the devices was not evaluated in the intended use population, and the scientific and clinical issues may not have been adequately addressed for these uses. Therefore, where devices are intended for use in professional healthcare settings, distinct performance parameters are proposed as recommendations in the draft guidance.

II. Significance of Guidance

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 Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use . 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use'', you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1755 to identify the guidance you are requesting.

IV. 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 part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. 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: January 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00023 Filed 1–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0529]

Guidance for Industry on Qualification Process for Drug Development Tools; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Qualification Process for Drug Development Tools.'' This guidance describes the qualification process for drug development tools intended for potential use, over time, in multiple drug development programs. The guidance provides a framework for interactions between FDA and sponsors to support work towards qualification of an identified drug development tool and creates a mechanism for formal review of data to qualify the tool and ensure that the evaluation is comprehensive and reliable.

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

ADDRESSES: Submit written requests for single copies of the 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 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: Shaniece Bowens, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4555, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Qualification Process for Drug Development Tools.'' The guidance describes the qualification process for drug development tools (DDTs) intended for potential use, over time, in multiple drug development programs.

In March 2006, FDA issued the ''Critical Path Opportunities Report and List,'' in which FDA described six key areas along the critical path to improved therapies and listed specific opportunities for advancement within these topic areas. The report noted that a new product development toolkit containing new scientific and technical methods was needed to improve the efficiency of drug development. Too often, attention to a needed DDT is delayed until the time when the registration study protocols are under development and the available DDTs are inadequate. Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers and patient reported outcome instruments. This guidance describes a formal