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for use in professional healthcare settings, distinct performance parameters are proposed as recommendations in the draft guidance.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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use .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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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This draft guidance refers to previously approved collections of information found in FDA regulations.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

process that FDA will use in working with sponsors of these tools to guide them as they refine the tools and rigorously evaluate them for use in the regulatory process.

A draft version of this guidance was issued in the **Federal Register** of October 25, 2010 (75 FR 65495). FDA received a number of comments, most of which focused on clarifications and further illustration of the qualification process. FDA reviewed all received comments carefully during the finalization process of the guidance; the Agency has made some clarifying changes in the final version of the guidance. Specifically, FDA provided general guidance on the qualification process, samples of what should be included in a qualification package, and examples of drug development tools. A new DDT, Animal Models under the Animal Rule, has been included and discussed in the final DDT guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the qualification process for drug development tools. 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 an approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains an information collection 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 information collection has been approved under the OMB control numbers 0910–0001 and 0910–0014. The information requested in the guidance is currently submitted to FDA to support medical product effectiveness (see 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6)).

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: December 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00028 Filed 1–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Application and other forms utilized by the National Health Service Corps (NHSC) Scholarship Program, the NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP).

OMB No.: 0915–0146—Revision.

Abstract: Administered by HRSA's Bureau of Clinician Recruitment and Service (BCRS), the National Health Service Corps (NHSC) Scholarship Program (SP), NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), provide scholarships or loan repayment to qualified students who are pursuing primary care health professions education and training. In return, students agree to provide primary health care services in medically underserved communities located in federally designated Health Professional Shortage Areas (HPSAs) once they are fully trained and licensed health professionals. Awards are made to applicants who demonstrate the greatest potential for successful completion of their education and training, as well as commitment to providing primary health care services to communities of greatest need. The program applications, forms, and supporting documentation are used to collect necessary information from applicants and participants that will facilitate the selection of the best qualified candidates for these competitive awards, and to monitor participants' enrollment in school or in postgraduate training.

Although some program forms vary (see program-specific burden charts below), general forms include: The Program Application; Academic and Non-Academic Letters of Recommendation; the Authorization to Release Information; and the Acceptance/Verification of Good Standing Report. Additional forms for the NHSC SP include the Data Collection Worksheet, which is completed by the educational institutions of program participants; the Post Graduate Training Verification Form (formerly the Deferment Request Form applicable for S2S participants), which is completed by program participants and their residency director; and the Enrollment Verification Form, which is completed by program participants and the educational institution for each academic term of the program.

Need and Proposed Use of the Information: The NHSC SP, S2S LRP, and NHHSP applications, forms, and supporting documentation are used to collect necessary information from