
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This draft guidance refers to previously approved collections of information found in FDA regulations.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 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910–0120; 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.

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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.

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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. 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