



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; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use." This document describes studies and criteria that FDA recommends be used when submitting premarket notifications (510(k)s) for self-monitoring blood glucose test systems (SMBGs) intended for over-the-counter (OTC) home use by lay-users. FDA intends for this document to serve as a guide for manufacturers in conducting appropriate performance studies and preparing 510(k)s for these device types.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit, the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No FDA-2013-D-1446 for "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Guidance for Industry and Food and Drug Administration Staff; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly

viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for single copies of the guidance to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Leslie Landree, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4623, Silver Spring, MD 20993-0002, 301-796-6147.

SUPPLEMENTARY INFORMATION:

I. Background

This document describes studies and criteria that FDA recommends be used when submitting 510(k)s for SMBGs which are for OTC home use by lay users. FDA intends for this document to serve as a guide for manufacturers in conducting appropriate performance studies and preparing 510(k)s for these device types. This document is not meant to address blood glucose monitoring test systems (BGMSs) which are intended for prescription point-of-care use in professional healthcare settings (e.g. hospitals, physician offices, long term care facilities, etc.). Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the guidance "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use" to address those device types.

Historically, FDA has not recommended different types of information in 510(k)s for BGMSs used by healthcare professionals as compared to SMBGs intended for home use by lay users. However, it has become increasingly clear that these different use settings have distinct intended use populations with unique characteristics that can impact device design specifications, and that manufacturers should take these unique characteristics into account when designing their devices. In order to distinguish between FDA recommendations for prescription-use BGMSs, which are intended for use in point-of-care professional healthcare settings, and SMBGs intended for use for self-monitoring by lay users, the Agency is issuing two separate guidances for: (1) Prescription use blood glucose meters, for use in point-of-care professional healthcare settings and (2) OTC SMBG devices intended for home use for self-monitoring by lay persons. FDA believes that in making this distinction, SMBGs can be better designed to meet the needs of their intended use populations, thereby providing greater safety and efficacy. While FDA recommends that the information described in this guidance be included in premarket submissions for SMBGs, submissions containing alternative information may be sufficient if able to demonstrate substantial equivalence to a legally marketed predicate device.

In the Federal Register of January 7, 2014 (79 FR 829), the Agency issued the draft guidance entitled "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use." In the Federal Register of April 9, 2014 (79 FR 19622), the Agency announced that the deadline for the comment period would be extended until May 7, 2014, to allow for more public comments on this draft guidance document. FDA considered the comments received on this draft guidance and FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1756 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. 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; and the collections of information in the guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

Dated: October 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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