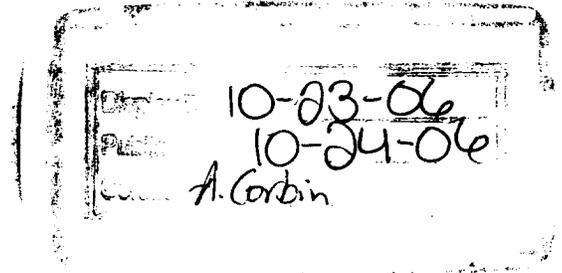


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0353]



Draft Guidance for Industry and Food and Drug Administration Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Draft Guidance for Industry and FDA Staff: Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems.” This draft guidance provides FDA’s recommendations concerning portable invasive blood glucose monitoring systems (BGMSs).

DATES: Submit written or electronic comments on this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Draft Guidance for Industry and FDA Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems ” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD, 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850, 240-276-0490 x117.

SUPPLEMENTARY INFORMATION:

I. Background

Portable invasive BGMS devices were introduced in the late 1970s and are considered one of the most important medical advances in diabetes care. This draft guidance document provides the FDA's recommendations concerning BGMS devices. In addition to recommendations for preparation of premarket notifications (510(k)), the draft guidance document discusses features of device design and risk management, including those relating to human factors. The draft guidance document, when finalized, is intended to complement International Standards Organization standards on risk management for medical devices and BGMSs. The scope of this draft guidance document includes BGMS devices, used in the quantitative measurement of glucose in blood by lay users at home or by professionals in hospitals and other point of care settings, to manage carbohydrate metabolism disorders including diabetes mellitus. When this guidance document is finalized, FDA expects that this guidance document will enable FDA to make more efficient and better-informed decisions based on more consistent data, and better

contribute to the marketing of more reliable, reproducible, and simple-to-use commercial devices.

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 the total product life cycle for portable invasive BGMSs. 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. To receive "Draft Guidance for Industry and FDA Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1603 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance

documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

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 USC 3501–3520). The collections of information in 21 CFR part 807 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, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: 10/11/06
~~October 11, 2006.~~

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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[Signature]