ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
External governmental and non-governmental organizations including non-profit organizations, trade associations, academic and research institutions, and the private sector.	Become a Partner	100	1	15/60	25
External governmental and non-governmental organizations including non-profit organizations, trade associations, academic and research institutions, and the private sector.	Become a Partner Follow-Up Questions.	100	1	30/60	50
Total	.....	.....	.....	75	

LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–00006 Filed 1–6–14; 8:45 am]

BILLING CODE 4163–18–P

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Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use''. This draft guidance document describes studies and criteria FDA recommends in premarket submissions for self-monitoring blood glucose test systems (SMBGs) which are for over-the-counter (OTC) use by lay-persons. 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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 7, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use''to the Division of Small Manufacturers, International, and Consumer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 self-monitoring blood glucose test systems (SMBGs) which are for over-the-counter (OTC) use by lay-persons. 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 systems (also called glucose meters) that measure blood glucose concentrations are used by millions of people with diabetes every day. These devices are used by patients in a variety of settings including in their homes, at work, and in schools.

Historically, FDA has not recommended different types of information in premarket submissions (510(k)s) for blood glucose monitoring systems used by medical professionals as compared to OTC devices intended for use by lay users. However, it has become increasingly clear that these different use settings create distinct intended use populations with unique characteristics and device design requirements. In order to distinguish between FDA recommendations for prescription use blood glucose meters, which are intended for use in point-of-care professional healthcare settings, and those intended for OTC self-monitoring by lay-persons, the Agency is issuing two separate draft guidances for (i) prescription use blood glucose meters, for use in point-of-care professional healthcare settings, and (ii) SMBG devices intended for OTC self-monitoring by lay-persons. FDA believes that in making this distinction, SMBG devices can be better designed to meet the needs of their intended use populations, thereby ensuring greater safety and efficacy.

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 Self-Monitoring Blood Glucose Test Systems for Over-the-Counter 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 ''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