

Amarillo and Wichita Falls. Additionally, for a period of 10 years, Respondent is required to give the Commission prior notice of plans to acquire any interest in a supermarket, or an interest in a supermarket, that has operated or is operating in Amarillo and Wichita Falls.

The sole purpose of this Analysis is to facilitate public comment on the proposed Consent Order. This Analysis does not constitute an official interpretation of the proposed Consent Order, nor does it modify its terms in any way.

By direction of the Commission.

Janice Podoll Frankle,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-14GB]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Become a Partner—New—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Office of Public Health Preparedness and Response (OPHPR) provide strategic direction, ongoing support, and coordination for CDC's portfolio of emergency preparedness and response activities. CDC and OPHPR work every day to keep America safe from all-hazards, focusing on chemical, biological, radiological and nuclear (CBRN) as well as naturally-occurring threats, both foreign and domestic.

OPHPR's mission is critically dependent on effectively engaging outside partners to maximize resources and overall impact. Therefore, OPHPR seeks ways to improve its current partner strategy to engage new partners. Forging strategic alliances with diverse stakeholders is critical as OPHPR works to keep America safe from all health, safety, and security threats. Health security is a national challenge that calls for a national, whole community solution.

New partners who do not have an explicit mission statement related to public health preparedness and response are difficult to identify; therefore, OPHPR must use a creative method that allows groups and individuals to self-identify their interest in partnerships—such as an online form housed on CDC's public Web site. By identifying new partners, OPHPR will strengthen its ability to collaborate with a broader audience of stakeholders thereby, strengthening our collective voice on public health preparedness issues to keep our nation's health secure. OPHPR will use the information submitted through this online form to determine who in our agency would be the best liaison for this potential

partner, and then follow up on this information with a phone call to further assess how we can begin building and effectively managing this new relationship.

CDC requests Office of Management and Budget (OMB) approval to collect information for three years.

Description

The "Become a Partner" template is a single, double-sided page that will be used as an online form for anyone voluntarily exploring how to partner with OPHPR. This form will dramatically reduce the burden on respondents and employees by allowing self-identification of partnership interests and collecting information to determine partnership needs and opportunities. The questions in the form specifically request name, address, phone, email, Web site, and a combination of five questions related to partnership interests. The questions asked will help determine if the interested party wants to receive information available through OPHPR, if they want to exchange information that is mutually beneficial for cross-promotion, if they coordinate any activities that support public health preparedness, and if they offer additional services to support public health (not already listed above). Finally, they will be asked to identify the most relevant partnership interests within OPHPR categories.

Ultimately, the form will allow OPHPR to identify and then engage interested partners in meaningful collaborations for the purpose of expanding, enhancing and sustaining public health preparedness and response infrastructure.

We estimate a total of 200 external governmental and non-governmental organizational respondents annually. The "Become a Partner" questionnaire is estimated to take 15 minutes and the "Become a Partner" follow-up questionnaire is estimated to take 30 minutes to complete. Therefore, the total estimated annualized burden for this information collection is estimated to be 75 hours.

There are no costs to respondents other than their time.

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.*

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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