

b. Age: Very young children, adolescents, and adults, including older adults (age >65 years)?

c. Pregnancy status: Pre-existing type 1 or type 2 diabetes?

d. Intensive insulin delivery: MDI or CSII?

TABLE 1—SUMMARY OF PROCESS MEASURES AND INTERMEDIATE AND CLINICAL OUTCOMES

Process measures	Intermediate outcomes	Clinical outcomes
<ul style="list-style-type: none"> <li>• Ratio of basal to bolus insulin .....</li> <li>• Frequency of adjusting insulin therapy .....</li> <li>• Adherence to insulin therapy/sensor use .....</li> <li>• Frequency of professional or allied health visits.</li> </ul>	<ul style="list-style-type: none"> <li>• Primary                             <ul style="list-style-type: none"> <li>• Hemoglobin A1c</li> </ul> </li> <li>• Secondary                             <ul style="list-style-type: none"> <li>• Hyperglycemia</li> <li>• Weight gain</li> <li>• Hypoglycemia frequency</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Microvascular*                             <ul style="list-style-type: none"> <li>• Retinopathy</li> <li>• Nephropathy</li> <li>• Neuropathy</li> </ul> </li> <li>• Macrovascular*                             <ul style="list-style-type: none"> <li>• Coronary heart disease</li> <li>• Cerebrovascular disease</li> <li>• Peropheral arterial disease</li> </ul> </li> <li>• Severe hypoglycemia</li> <li>• Quality of life</li> <li>• Fetal outcomes †</li> <li>• Maternal pregnancy outcomes                             <ul style="list-style-type: none"> <li>• C-section rates</li> </ul> </li> </ul>

\* We will only include objective assessments of microvascular and macrovascular outcomes (i.e., we will be excluding patient self-reported microvascular and macrovascular outcomes).

† Fetal outcomes include gestational age, birth weight, frequency of neonatal hypoglycemia, birth trauma, major and minor anomalies, and admission to a neonatal intensive care unit.

For each KQ we will identify:  
Population(s):

Adults, adolescents, and children with type 1 or type 2 diabetes mellitus and pregnant women with pre-existing diabetes treated with insulin therapy.

1. We will use age ranges prescribed by the Juvenile Diabetes Research Foundation (<8 years [very young children], 8–14 years [children], 14–25 years [adolescent], and >25 years [adults]); however, our final definitions will be guided by those used in the literature that is reviewed.

2. If available, we will examine data among populations of older adult (>65 years).

Interventions:

The interventions of interest are CSII (see Appendix 2 for a list of insulin pumps and models) and rt-CGM (see Appendix 3 for a list of monitors).

1. We will not be including the following devices because they are no longer used in the United States:

- a. GlucoWatch continuous glucose meter
- b. Insulin pumps with regular insulin Comparators:

All studies must have a concurrent comparison group.

1. CSII would be compared with MDI, which will be defined as at least three injections of basal and rapid-acting insulin per day.

2. rt-CGM would be compared with SMBG, which will be defined as at least three fingersticks per day.

Outcomes measures for each KQ:

- 1. Process measures
  - a. Ratio of basal to bolus insulin
  - b. Frequency of adjustments to insulin therapy

c. Adherence to insulin therapy/sensor use

d. Frequency of professional or allied health visits Intermediate outcomes

- HbA1c

a. Hyperglycemia

b. Weight gain

c. Hypoglycemia frequency

Clinical Outcomes

- Objective assessments of microvascular outcomes (retinopathy, nephropathy, and neuropathy)

a. Objective assessments of macrovascular outcomes (coronary heart disease, cerebrovascular disease, and peripheral arterial disease)

b. Severe hypoglycemia

c. Quality of life

d. Fetal outcomes (gestational age, birth weight, frequency of neonatal hypoglycemia, birth trauma, major and minor anomalies, and admission to a neonatal intensive care unit)

e. Maternal pregnancy outcomes (cesarean section rates)

Timing: Usage of a device for at least 24 hours.

Settings: Outpatient setting.

Dated: June 10, 2011.

**Carolyn M. Clancy,**

*AHRQ, Director.*

[FR Doc. 2011-15580 Filed 6-21-11; 8:45 am]

**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0110]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug Advertisements**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Prescription Drug Advertisements” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 24, 2011 (76 FR 4117), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0686. The approval expires on June 30, 2014. A

copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 17, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-15592 Filed 6-21-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0464]

#### **Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption and Premarket Approval Applications for Low Glucose Suspend Device 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 document entitled “Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems.” This draft guidance document provides industry and Agency staff with recommendations that are intended to improve the safety and effectiveness of LGS Device Systems. 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 September 20, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled “Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems” 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:**

Charles Zimliki, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2556, Silver Spring, MD 20993-0002, 301-796-6297.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Diabetes mellitus has reached epidemic proportions in the United States and more recently, worldwide. The morbidity and mortality associated with diabetes is anticipated to account for a substantial proportion of health care expenditures. Although there are many devices available that help patients manage the disease, FDA recognizes the need for new and improved devices for treatment of diabetes. One of the more advanced diabetes management systems is an artificial pancreas device system. An artificial pancreas system is a type of autonomous system that adjusts insulin infusion based upon the continuous glucose monitor via control algorithm. There are a variety of types of artificial pancreas systems depending upon the nature of the control algorithm. They can be generally divided into three categories, LGS, Treat-to-Range, and Treat-to-Target. In this notice, FDA is announcing a draft guidance for the first type of artificial pancreas, the LGS system. An LGS system links a continuous glucose monitor to an insulin pump and automatically reduces or suspends insulin infusion temporarily based upon specified thresholds of measured glucose levels. This type of system is designed to reduce or mitigate the likelihood of a hypoglycemic event. There are significant challenges in creating an autonomous system, which were discussed in a joint FDA and National Institutes of Health (NIH) artificial pancreas workshop on November 10, 2010 (information available at: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/>

[ucm226251.htm](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm226251.htm). Currently, there is no FDA-approved artificial pancreas for home use. This workshop sought feedback on ways to overcome the obstacles towards developing an artificial pancreas. The feedback received from this workshop and the continued communication with investigators in this field has provided valuable input for FDA’s first guidance for a LGS device. This guidance will outline considerations for development of clinical studies, and recommends elements that should be included in IDE and PMA applications, focusing on critical elements of safety and effectiveness for approval of this device type. The guidance includes one suggested approach to support safety and effectiveness, but given the early stage of this technology, FDA is open to considering alternative study design approaches and seeks comments regarding alternative approaches. FDA particularly seeks comments regarding the validity of the Continuous Glucose Monitor based event for hypoglycemia endpoint, pivotal study design, and patient population. As the LGS system is one of three types of artificial pancreas systems, comments to the LGS guidance will not only assist FDA in finalizing guidance on LGS systems, but also assist in developing future draft guidance for the other types of artificial pancreas systems. FDA continues to work with the investigators in this field and is developing a second guidance to address the remaining artificial pancreas device systems.

##### **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 LGS Device systems. 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 “Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket