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Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption and Premarket Approval Applications for Low Glucose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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low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 This draft guidance document provides industry and Agency staff with recommendations that are intended to improve the safety and effectiveness of LGS Device Systems. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 20, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Low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Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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*. 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

Approval (PMA) Applications for Low Glucose Suspend (LGS) Device 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 301–847–8149 to receive a hard copy. Please use the document number 1748 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations and guidance documents. 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 parts 801 and 809 are currently approved under OMB control number 0910–0485, the collections of information in 21 CFR part 812 are currently approved under OMB control number 0910–0078, and the collections of information in 21 CFR part 814 are currently approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 16, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–15541 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–0469]

Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering To Optimize Medical Device Design; 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: Applying Human Factors and Usability Engineering to Optimize Medical Device Design.'' The recommendations in this guidance are intended to improve the safety and effectiveness of devices and reduce use error. 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 § 10.115(g)(5) (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 electronic or written comments on the draft guidance by September 19, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design'' 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: Molly Story, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2533, Silver Spring, MD 20993–0002, 301–796–1456, e-mail: *molly.story@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

To understand use-related hazards, it is necessary to have an accurate and complete understanding of how a device will be used. Understanding and optimizing how people interact with technology is the subject of human factors engineering (HFE) and usability engineering (UE). HFE/UE considerations that are important to the development of medical devices include three major components of the device-user system: (1) Device users, (2) device use environments, and (3) device user interfaces.

For safety-critical technologies such as medical devices, the process of eliminating or reducing design-related use problems that contribute to or cause unsafe or ineffective medical treatment is part of a process for controlling overall risk. For devices where harm could result from ''use errors,'' the dynamics of user interaction are safety-related and should be components of risk analysis and risk management. By incorporating these considerations into the device development process, manufacturers can reduce the overall risk level posed by their devices, thus decreasing adverse events associated with the device, and avoid potential device recalls.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the Agency's current thinking on human factors engineering for medical devices. 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 is available for all CDRH guidance documents 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: Applying Human Factors and Usability Engineering to Optimize Medical Device Design.'' 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 301–847–8149 to receive a hard copy. Please use the document number 1757 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These