4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Guidance for Industry and Food and Drug Administration Staff; The Content of Investigational Device Exemption and Premarket Approval Applications for Artificial Pancreas Device Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems." FDA is issuing this guidance to inform industry and Agency staff of its recommendations for analytical and clinical performance studies to support premarket submissions for artificial pancreas systems.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas 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 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:

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10903 New Hampshire Ave.,

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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 a control algorithm.

On June 22, 2011 (76 FR 36542), FDA announced 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 Applications (PMA) for Low Glucose Suspend (LGS) Device Systems." On December 6, 2011 (76 FR 76166), FDA announced the availability of the draft guidance document entitled "The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems." Ninety-seven sets of comments were received in total for both guidance documents. In response to comments, FDA made clarifying edits in several sections. Based on the similarities between the two draft guidance documents and the comments received, these two documents have been combined into one guidance document, which provides industry and Agency staff with recommendations for developing premarket submissions for artificial pancreas device systems (APDS) and is the subject of this Federal Register document. The guidance outlines considerations for development of clinical studies, and recommends elements that should be included in IDE and PMA applications for artificial pancreas systems, including threshold suspend systems (also known as low glucose suspend systems), single hormonal control systems, and bihormonal control systems. This guidance focuses on critical elements of safety and effectiveness for approval of this device type, while keeping in mind the risks diabetic patients face everyday.

Artificial pancreas device systems are class III devices and require the submission of a PMA. All components of the APDS (insulin pump, continuous glucose monitoring system, blood glucose device, and control algorithm and signal processing functional component) are considered essential components of the system and will be regulated as class III devices when used as part of an APDS. As such, all information sufficient for approval of the components as

part of the system should be provided in the PMA submission (e.g., manufacturing information, specifications, etc.).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the content of IDE and PMA applications for artificial pancreas 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 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 the document "The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems," 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 1759 to identify the guidance you are requesting.

IV. Paperwork Reduction Act

This guidance refers to currently approved collections of information found in FDA regulations and guidance documents. These collection 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 54.4 are approved under OMB control number 0910-0396; the collections of information in 21 CFR 56.115 are approved under OMB control number 0910-0130; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 814 are approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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: November 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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