

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>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 19, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-28430 Filed 11-21-12; 8:45 am]

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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:

Stayce Beck, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5609, Silver Spring, MD 20993, 301-796-6514.

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.

[FR Doc. 2012–28339 Filed 11–21–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates and Times: December 7, 2012, 1:00 p.m.–5:00 p.m. EST.

Place: Webinar and Conference Call Format.

SUPPLEMENTARY INFORMATION: *Status:* The meeting will be open to the public. The conference call access will be limited only by availability of telephone ports.

Purpose: The members of the ACICBL will begin the planning required to develop the legislatively mandated 13th Annual Report to the Secretary of Health and Human Services and Congress. The meeting objectives are to: (1) Focus on a relevant topic that will enhance the mission of the Title VII training programs; (2) develop an outline that will inform the development of the 13th Annual Report; (3) provide an update on training programs; and (4) provide an update on the 12th Annual Report.

Agenda: The ACICBL agenda includes an opportunity for each member to offer ideas for the upcoming report, along with identifying consultants in specific areas who could provide expert testimony. The staff writer provided by the Health Resources and Services Administration (HRSA), Bureau of Health Professions, will offer a strategy for outlining the upcoming report. The agenda will be available days prior to the meeting on the HRSA Web site (<http://www.hrsa.gov/advisorycommittees/bhpradvisory/acicbl/acicbl.html>). Agenda items are subject to change as priorities dictate.

Individuals who plan to participate on the webinar should register at least one day prior to the meeting, using the following webinar information: <https://hrsa.connectsolutions.com/r5x1ckknl6>. The conference call-in number is 1–800–857–5750, using the participant passcode 6694174.

Requests to make oral comments or provide written comments to the ACICBL should be sent to Dr. Joan Weiss, Designated Federal Official, at least 3 days prior to the meeting using

the address and phone number below. Individuals who plan to participate on the conference call or webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments. Interested parties should refer to meeting subject as the HRSA Advisory Committee on Interdisciplinary, Community-Based Linkages.

FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the ACICBL should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Professions, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9C–05, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–6950; or (3) email jweiss@hrsa.gov. The web address for information on the Advisory Committee is <http://www.hrsa.gov/advisorycommittees/bhpradvisory/acicbl/acicbl.html>.

Dated: November 16, 2012.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2012–28378 Filed 11–21–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 6, 2012, 1:00 p.m. to 4:45 p.m. EDT.

Place: Parklawn Building (and via audio conference call), 5600 Fishers Lane, Conference Room 10–65, Rockville, MD 20857.

The ACCV will meet on Thursday, December 6, 2012, from 1:00 p.m. to 4:45 p.m. (EDT). The public can join the meeting via audio conference call by dialing 1–800–369–3104 on December 6 and providing the following information:

Leader's Name: Dr. Vito Caserta.

Password: ACCV.