

Association and the Gases and Welding Distributors Association voluntarily submitted to the Agency its views on implementation of the medical gas provisions of FDASIA. FDA plans to place these comments in the public docket so they are readily available to all interested members of the public. FDA expects to place all additional submissions containing recommendations on how the Agency should implement the medical gas provisions of FDASIA in this docket, and directs the public to submit all comments related to these provisions to this docket. This docket will be open for comments for 1 year from the date of publication of this notice. In addition, as FDA implements the medical gas provisions of FDASIA, FDA plans to open other dockets. For example, we plan to issue a separate **Federal Register** notice in the future to provide the public with an opportunity to submit comments on section 1112 of FDASIA. Section 1112(a)(1) of FDASIA provides that not later than 18 months after the date of the enactment of FDASIA, the Secretary, after obtaining input from medical gas manufacturers and any other interested members of the public, must determine whether any changes to the Federal drug regulations are necessary for medical gases.

## II. Comments

Interested persons may submit either written comments 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 19, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-1120]

#### Draft Guidance for Industry on Vaginal Microbicides: Development for the Prevention of Human Immunodeficiency Virus Infection; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Vaginal Microbicides: Development for the Prevention of HIV Infection." The purpose of this guidance is to assist sponsors in all phases of development of vaginal microbicides for the prevention of human immunodeficiency virus (HIV) infection. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of vaginal microbicides.

**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 February 21, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

**FOR FURTHER INFORMATION CONTACT:** Charu Mullick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6365, Silver Spring, MD 20993-0002, 301-796-1500.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Vaginal Microbicides: Development for the Prevention of HIV Infection." This guidance addresses nonclinical development, early phases of clinical development, phase 3 trial considerations, and safety considerations in vaginal microbicide development, including safety considerations in adolescent and pregnant populations. The guidance also provides some information on approaches for developing combination microbicide products such as drug-drug combinations, drug-device combinations containing a microbicide, or combination products containing a microbicide that are intended for multiple indications. With the recent approval of oral emtricitabine/tenofovir for HIV pre-exposure prophylaxis (PrEP), the effect of oral PrEP on microbicide trial designs is an emerging topic. The guidance discusses this issue; however, it should be noted the pertinent sections may be revised as FDA takes into consideration evolving opinions in the prevention field as well as public comments on this topic.

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 developing vaginal microbicides for preventing HIV transmission. 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 statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 part 312 have been approved under OMB control number 0910-0014, and the collections of information referred to in the guidance for clinical trial sponsors entitled "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under OMB control number 0910-0581.

## III. Comments

Interested persons may submit either written comments regarding the draft guidance 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>.

#### 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.

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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)