

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Towards an Artificial Pancreas: A Food and Drug Administration, National Institutes of Health, Juvenile Diabetes Research Foundation Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the National Institutes of Health (NIH) and the Juvenile Diabetes Research Foundation (JDRF), is holding a public workshop focused upon the state of the art in the research and development of an artificial pancreas. The public workshop entitled “Towards an Artificial Pancreas: A Food and Drug Administration, National Institutes of Health, and Juvenile Diabetes Research Foundation Workshop” will provide a public forum for discussing the progress and remaining challenges in the development of closed-loop systems designed to regulate glycemic control, as an aid in the management of diabetes mellitus. It is intended to provide stakeholders with information that will accelerate the development of an artificial pancreas.

DATES: The public workshop will be held on July 21, 2008, from 7:55 a.m. to 6 p.m., and on July 22, 2008, from 8 a.m. to 12:45 p.m. Registration is available until 5 p.m. on June 20, 2008 (See **REGISTRATION TO ATTEND THE PUBLIC WORKSHOP**).

ADDRESSES: The public workshop will be held at the Lister Hill Auditorium on the NIH Campus (<http://www.nih.gov/science/campus/index.html>) located at 9000 Rockville Pike, Bethesda, MD 20892.

Parking on the NIH campus is limited. Attendees are encouraged to take public transportation. There is limited parking available at the Natcher Building. See <http://www.nih.gov/about/directions.htm> for more information.

FOR FURTHER INFORMATION CONTACT: Arleen Pinkos, Center for Devices and Radiological Health (HFZ-440), 2098 Gaither Rd., Rockville, MD 20850, 240-276-0702, FAX 240-276-0651, e-mail: arleen.pinkos@fda.hhs.gov.

REGISTRATION TO ATTEND THE PUBLIC WORKSHOP: Those interested in attending the public workshop may register online at <http://www.blsm meetings.net/artificialpancreas08/reg.cfm>. There is no registration fee to attend the meeting; however, all participants must submit a registration form. Space is limited, so please submit your registration early to reserve a space. Registration will be accepted through June 20, 2008; however, onsite registration will be permitted on a space-available basis.

Persons without Internet access may call Akia Richardson at 301-313-0244 ext. 49, by June 20, 2008, to register for onsite attendance.

If you need special accommodations due to a disability, please contact L'Tonya Frazier at 301-594-4453 at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The artificial pancreas is one of FDA's Critical Path Initiatives, a program dedicated to accelerating the availability of much needed medical products. The Interagency Artificial Pancreas Working Group, a group of multi-disciplined scientists and clinicians from FDA and NIH, was established to

support this initiative. The goals of the Artificial Pancreas Initiative are twofold: to provide infrastructure for narrowing the gap between basic biomedical knowledge and clinical application of novel technologies, and to cross-fertilize and partner with stakeholders in order to identify and overcome the clinical and scientific challenges to the development of an artificial pancreas. Through collaborative efforts, such as this workshop, the group strives to develop innovative strategies to achieve their goals.

II. Agenda

World renowned experts will present information on topics that are instrumental to the development of an artificial pancreas, and each session will be followed by roundtable discussions. Session topics will include:

- State of the art design of closed-loop glycemetic control systems
- Results of recently conducted clinical trials
- Clinical trial design, including how to define successes and failures of closed-loop systems
- Algorithms and in silico models
- Engineering challenges
- Patient considerations
- Metabolic monitoring
- Use of closed-loop systems in non-diabetic intensive care patients
- Paths for developing marketable closed-loop systems

The agenda for this public workshop is available on the internet at <http://www.blsm meetings.net/artificialpancreas08/agenda.pdf>.

More information about this public workshop is available at <http://www.blsm meetings.net/artificialpancreas08>.

Dated: April 21, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

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