

record of the ACBSCT meeting. Meeting summary notes will be made available on the HRSA's Program Web site at [http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory\\_Council/index.html](http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html).

Those planning to attend are requested to register in advance. The draft meeting agenda and a registration form are available on the HRSA's Program Web site at [http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory\\_Council/index.html](http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html).

Registration also can be completed electronically at <http://www.acbsct.com> or submitted by facsimile to Lux Consulting Group, Inc., the logistical support contractor for the meeting, at fax number (301) 585-7741 Attn: Tristan Alexander. Individuals without access to the Internet who wish to register may call Tristan Alexander at (301) 585-1261.

#### FOR FURTHER INFORMATION CONTACT:

Patricia Stroup, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857; telephone (301) 443-1127.

Dated: October 6, 2010.

**Wendy Ponton,**

*Director, Office of Management.*

[FR Doc. 2010-25646 Filed 10-12-10; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the CDC announces the following meeting of the aforementioned committee:

*Time and Date:* 8:30 a.m.–3 p.m., October 28, 2010.

*Place:* CDC, 1600 Clifton Road, NE., Building 21, Rooms 1204 A/B, Atlanta, Georgia 30333.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people. The public is welcome to participate during the public comment period. The public comment period is tentatively scheduled for 2:30 to 2:45 p.m.

*Purpose:* The committee will provide advice to the CDC Director on strategic and other broad issues facing CDC.

*Matters to be Discussed:* The ACD, CDC will receive updates from the Global Workgroup; State, Tribal, Local and Territorial Workgroup; Surveillance and Epidemiology Workgroup; and the Policy Workgroup. The Ethics Subcommittee and National Biosurveillance Advisory Subcommittee will provide updates on their current activities.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Carmen Villar, M.S.W., Designated Federal Officer, ACD, CDC, 1600 Clifton Road, NE., M/S D-14, Atlanta, Georgia 30333. Telephone 404/639-7000. *E-mail:* [GHickman@cdc.gov](mailto:GHickman@cdc.gov). The deadline for notification of attendance is October 25, 2010.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 5, 2010.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2010-25703 Filed 10-12-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Innovations in Technology for the Treatment of Diabetes: Clinical Development of the Artificial Pancreas (an Autonomous System); Public Workshop

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) and the National Institutes of Health (NIH) are announcing a public workshop entitled "Innovations in Technology for the Treatment of Diabetes: Clinical Development of the Artificial Pancreas (an Autonomous System)." The topics to be discussed are the current state of device systems for autonomous systems for the treatment of diabetes mellitus, the challenges in developing this expert system using existing technology, a discussion of the clinical expectations and success criteria for these systems, and a discussion of development plans for the transition of this device system toward an outpatient setting.

*Date and Time:* The public workshop will be held on November 10, 2010, from 8 a.m. to 5 p.m. Persons interested in attending this meeting must register by 5 p.m. on November 3, 2010.

*Location:* The meeting will be held at the Hilton Washington, DC North/Gaithersburg Hotel, 620 Perry Pkwy., Gaithersburg, MD 20877.

*Contact:* Charles Zimlik, Food and Drug Administration, Center for Devices and Radiological Health (CDRH), 10903 New Hampshire Ave., Bldg. 66, rm. 2556, Silver Spring, MD 20993-0002, 301-796-6297, Fax: 301-847-8109, *e-mail:* [Charles.Zimlik@fda.hhs.gov](mailto:Charles.Zimlik@fda.hhs.gov).

*Registration:* Registration is free and will be on a first-come, first-served basis. To register for the public workshop, webinar or onsite attendance, please visit the following Web site: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm226251.htm> (select the appropriate meeting from the list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. For those without Internet access, please call Victoria Wagman at 301-796-6581 to register. Registration requests should be received by 5 p.m. on November 3, 2010. Early registration is recommended because seating is limited and therefore FDA/NIH may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public meeting will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan (e-mail: [Susan.Monahan@fda.hhs.gov](mailto:Susan.Monahan@fda.hhs.gov)) at least 7 days in advance.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

CDRH has undertaken an initiative to proactively facilitate medical device innovation to address unmet public health needs. As part of this initiative, CDRH with NIH have focused on the development of the artificial pancreas (or Autonomous System) for the treatment of diabetes mellitus. An artificial pancreas is a medical device that links a glucose monitor to an insulin infusion pump where the pump automatically takes action (using a control algorithm) based upon the glucose monitor reading. As control algorithms can vary significantly, there are a variety of artificial pancreas systems currently under development. These systems can range from low glucose suspend, to control-to-range, to control-to-target, to bihormonal control where each device has different purposes or intended uses for controlling blood sugars. In addition, most research in this area uses existing medical device technology, which might limit the performance and evaluation of these systems. Given these device limitations, preliminary research has focused on evaluating these systems in

a hospital-based environment, where the risks to the patient are minimized. CDRH and NIH seek feedback on ways to overcome obstacles in the development of an artificial pancreas and what might be considered reasonable clinical expectations for systems considering the available existing technology.

This public workshop is to seek input from a wide range of constituencies including but not be limited to industry, academia, patient/consumer advocacy groups, professional organizations, and other State and Federal bodies under aligned public health missions, to address the issues outlined in this notice. During the public workshop, there will be an open dialogue between Federal Government and experts from the private and public sectors regarding the topics described in this document. Workshop participants will not be expected to develop consensus recommendations, but rather to provide their perspectives on the clinical development of these device systems.

## II. Issues for Discussion

The workshop will focus on three topics: (1) Technical considerations when developing a clinical study design; (2) expectations of the various artificial pancreas device systems; and (3) a discussion of the various development plans for the Artificial Pancreas System. The discussion of these general topics should not be limited by current statutes or regulations and will include, but not be limited to, discussion of the preceding questions.

## III. Where can I find more information about this public workshop?

Background information on the public workshop, registration information, the agenda, and other relevant information will be posted, as it becomes available, on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm226251.htm>.

## IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and

Drug Administration, 5600 Fishers Lane, Rm. 6-30, Rockville, MD 20857.

Dated: October 5, 2010.

**Nancy K. Stade,**

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

[FR Doc. 2010-25600 Filed 10-12-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM): Workshop Series on Best Practices for Regulatory Safety Testing: Assessing the Potential for Chemically Induced Eye Injuries and Chemically Induced Allergic Contact Dermatitis (ACD)**

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), Department of Health and Human Services.

**ACTION:** Announcement of a Workshop Series.

**SUMMARY:** NICEATM and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announce a planned series of workshops on "Best Practices for Regulatory Safety Testing." The first two workshops in this series, "Best Practices for Assessing the Potential for Chemically Induced Eye Injuries" and "Best Practices for Assessing the Potential for Chemically Induced Allergic Contact Dermatitis," are planned for January 19 and 20, 2011, respectively. These one-day workshops will help participants gain a practical understanding of the theory and application of available *in vitro* and *in vivo* alternative test methods that can be used to evaluate the hazard potential of chemicals and products while avoiding or minimizing animal use and animal pain and distress. Participants will learn the strengths and weaknesses of available alternative test methods, become familiar with the types of data they provide, and learn how to use these data in regulatory safety assessments. Workshop topics will be of particular interest to those involved in conducting safety tests for chemically induced eye injuries and/or chemically induced ACD, those responsible for reviewing and approving study protocols prior to testing, and regulators who are expected to review data generated by the tests. The workshops are free and open to the

public with attendance limited only by the space available. Those interested may register for one or both workshops.

**DATES:** The workshop on "Assessing the Potential for Chemically Induced Eye Injuries" will be held on January 19, 2011. The workshop on "Assessing the Potential for Chemically Induced Allergic Contact Dermatitis" will be held on January 20, 2011. Sessions for both workshops will begin at 8:30 a.m. and end at approximately 5 p.m. Individuals who plan to attend either or both workshops are asked to register with NICEATM by January 6, 2011.

**ADDRESSES:** The workshops will be held at the William H. Natcher Conference Center, 45 Center Drive, NIH Campus, Bethesda, MD 20892. Persons needing special assistance in order to attend, such as sign language interpretation or other reasonable accommodation, should contact 919-541-2475 voice, 919-541-4644 TTY (text telephone), through the Federal TTY Relay System at 800-877-8339, or e-mail to [niehsoeeo@niehs.nih.gov](mailto:niehsoeeo@niehs.nih.gov). Requests should be made at least 14 days before the event.

#### **FOR FURTHER INFORMATION CONTACT:**

Correspondence should be sent by mail, fax, or e-mail to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD K2-16, Research Triangle Park, NC 27709, (phone) 919-541-2384, (fax) 919-541-0947, (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

To protect workers and consumers, regulatory agencies require testing to determine if chemicals and products may cause illnesses or injuries. Each year, approximately 2 million eye injuries occur in the U.S., of which more than 40,000 result in permanent visual impairment. Data on consumer product-related eye injuries indicate that the most common products causing eye injuries in children under the age of 10 are household cleaning chemicals and other chemical products. ACD is also a significant concern because skin diseases, including ACD, constitute the second most common category of occupational disease. ACD frequently develops in workers and consumers exposed to skin sensitizing products and chemicals, results in lost workdays, and can significantly diminish quality of life.

To address these concerns, regulatory authorities require safety testing that can identify substances that may present these hazards. Tests for ocular and ACD hazards are two of the four most frequently conducted product safety