and the number of requests, it may be necessary to limit the time of each presenter.

Contact Person for More Information: Claudine Johnson, Clerk, Lead Poisoning Prevention Branch, Division of Environmental Emergency Health Services, National Center for Environmental Health, CDC, 4770 Buford Hwy., NE., Mailstop F–60, Atlanta, GA 30341, *Telephone:* (770) 488–3629, Fax (770) 488–3635.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 27, 2008.

Diane Allen,

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

[FR Doc. E8–4085 Filed 2–29–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0118]

Draft Guidance for Industry on Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention.'' The draft guidance provides recommendations for industry for developing drugs and therapeutic biologics for the prevention and treatment of diabetes mellitus. Because diabetes mellitus has reached epidemic proportions in the United States, FDA recognizes the need for new products that can be used as part of a comprehensive treatment strategy in the treatment and prevention of diabetes. In addition to the draft guidance, FDA plans to convene a public advisory committee meeting to specifically discuss new approaches for the development of products for the treatment of diabetes, with particular emphasis on the design and implementation of studies to assess long-term cardiovascular risks and benefits of these new products. FDA plans to announce the meeting date in a future issue of the **Federal Register**.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 2, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ilan Irony, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3100, Silver Spring, MD 20993–0002, 301–796–2290.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention.'' Although a number of drugs are available for the treatment of type 1 and type 2 diabetes, many patients remain inadequately controlled, and thus are exposed to a higher risk of long-term complications. This draft guidance provides recommendations on the following topics related to the treatment of type 1 and type 2 diabetes mellitus:

- Diabetes-specific preclinical studies;
- Different study designs in different phases of drug development for both type 1 and type 2 diabetes;
- Study endpoints in the assessment of pharmacokinetic/pharmacodynamic profiles and for efficacy and safety assessment in treating patients with diabetes;
- Study population considerations in different phases of development;
- Sample sizes;
- Study duration; and
- Specific statistical issues related to development of drugs and biologics intended for the treatment of diabetes.

The draft guidance also provides recommendations regarding the development of products for the prevention of both type 1 and type 2 diabetes.

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 the treatment and prevention of diabetes mellitus. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 25, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3974 Filed 2–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for information.

SUMMARY: HRSA, Healthcare Systems Bureau, Division of Transplantation (DoT) is in the process of information-

gathering to assist in determining whether it should engage in rulemaking with respect to vascularized composite allografts, described more fully below. The purpose of this solicitation is to receive feedback from stakeholders and the public on the following questions: (1) Whether vascularized composite allografts should be included within the definition of organs covered by the regulations governing the operation of the Organ Procurement and Transplantation Network (OPTN) (referred to here as the ''final rule''), and regulated as such, and the likely impact of such an amendment; (2) whether vascularized composite allografts should be added to the definition of human organs covered by section 301 of the National Organ Transplant Act of 1984, as amended, (NOTA) and the likely impact of such an addition; and (3) if either of these changes are pursued, the optimal way to define vascularized composite allografts for the above-described purposes.

This Request for Information is limited to information-gathering and is not a proposal to make any determinations regarding Federal oversight of vascularized composite allografts.

DATES: Written comments must be received at HRSA by May 2, 2008. Comments will be made publicly available by submitting a written request to the address below.

In addition, HRSA will hold a meeting to which the public and all stakeholders are invited for discussion and recommendations about the issues described above. The meeting will be held on Friday, April 4, 2008, from 10 a.m. to 4 p.m., at the Parklawn Building, 5600 Fishers Lane, Rockville, MD 20057.

ADDRESSES: Please send all written comments to James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room12C–06, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov.*

Requests to attend the meeting in person should be addressed to Elizabeth Ortiz-Rios, M.D., M.P.H., Chief Medical Officer, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C–06, Rockville, Maryland 20857; telephone (301) 443–4423; fax (301) 594–6095; or e-mail: *EOrtiz-Rios@hrsa.gov.* A call-in number will be provided for individuals who would like to participate by phone. The call-in information will be posted in the 'Highlights' section on the home page of *http://www.organdonor.gov.* If you plan to participate by phone, we request that you notify Dr. Ortiz-Rios by e-mail at *EOrtiz-Rios@hrsa.gov* no later than March 24, 2008, so that we can better estimate the number of phone lines that will be needed. Please include in the subject line of electronic correspondence ''Vascularized Composite Allografts.''

Docket: For access to the docket to read background documents or comments received, phone (301) 443–7577 to schedule an appointment to view public comments.

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, at the contact information cited above.

SUPPLEMENTARY INFORMATION:

Background and General Questions

The first successful hand transplant in the United States was performed in 1999. Worldwide there have been over two dozen limb transplants, at least two transplants of portions of the face, and a small number of transplants of other such anatomical parts (e.g., abdominal wall, vascularized skeletal muscle, uterus, digits, thymus). Although the body parts involved vary significantly, two characteristics that are shared in such transplants are that they are susceptible to ischemia (damage or death from lack of blood flow) and their need for revascularization, done through a surgical reconnection of blood vessels to accomplish the transplant, as opposed to secondary ingrowth of vessels. In viable vascularized transplants, immunosuppression is necessary to prevent or treat rejection. This immunosuppression has risks, which have been justified in patients needing organs as presently defined in the final rule, because of their lifesaving potential. In the past, the risks of immunosuppression have inhibited transplantation of vascularized composite allografts because the risks associated with the prolonged use of immunosuppressive drugs were thought to exceed the expected benefits of the transplant. However, the powerful impact these transplants can have to overcome and improve the quality of life for individuals with grievous disabilities has become increasingly apparent. Coupled with this, immunosuppressive management for these transplants has improved so that risks associated with immunosuppression, such as cancer, infection, or other morbidities in recipients are lessened considerably. For these reasons, it is likely that the numbers of vascularized composite allografts transplanted will increase in the future. Given this anticipated increase, HRSA is considering the advisability of proposing that such transplants (i.e., transplants of vascularized composite allografts) be regulated under the final rule and governed by section 301 of NOTA.

HRSA is considering whether to propose that viable vascularized composite allografts, or body segments, be considered organs subject to the oversight of the OPTN under the authority of the final rule. This might be accomplished by adding vascularized composite allografts to the final rule's definition of organs through rulemaking. Currently, the final rule defines covered organs as ''a human kidney, liver, heart, lung, or pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled 'For use in organ transplantation only.' '' Once a body part is considered an organ under the final rule, transplants involving such organs are subject to the requirements of the final rule. For example, entities performing transplants with the organs must receive designation as an organ-specific designated transplant program within an OPTN member institution. In addition, OPTN members must comply with the final rule's data submission requirements with respect to the transplants performed. In addition, OPTN members are subject to oversight by the OPTN contractor for compliance with OPTN policies regarding donor screening and allocation, and may be subject to enforcement actions for violations of such policies.

The Definition of Organs Under the Final Rule

HRSA is seeking feedback from stakeholders and from the public about the advisability of exploring rulemaking to include vascularized composite allografts within this definition of organs, as well as the potential ramifications of such a change. If, upon consideration of public comments, HRSA is persuaded that such a change may be warranted, HRSA may initiate rulemaking setting forth a more specific set of proposals.

For example, HRSA is interested in the public's assessment of the likely impact if OPTN policies concerning issues such as membership designation to receive organs, the retrieval of organs, allocation of organs, data collection and reporting, and OPTN policy compliance oversight were extended to vascularized composite allograft transplants. HRSA seeks feedback concerning whether regulation under the OPTN final rule would be effective in addressing special safety and allocation issues presented by vascularized composite allograft transplants as the field grows. Further, HRSA is interested in the public's assessment as to whether the clinical aspects of transplants of such vascularized composite allografts are more analogous to transplants of organs, as defined currently by the final rule, than to conventional tissue transplantation without surgical revascularization.

Presently, it is HRSA's understanding that these transplants of vascularized composite allografts are done by individual arrangements with local organ procurement organizations (OPOs) to allow retrieval of the needed structure during routine deceased donor organ retrievals. However, some of these vascularized composite allografts, e.g., testes, ovaries, or other endocrine glands, may come from living donors. HRSA is interested in perceived vulnerabilities concerning the current regulatory status of such transplants and the potential benefits of subjecting such transplants to the oversight of the OPTN and HRSA under the final rule.

The Definition of Human Organs Under Section 301 of NOTA

HRSA is also seeking feedback as to whether it should explore rulemaking to add vascularized composite allografts to the definition of human organs covered by section 301 of NOTA, as well as the potential consequences of such an action. Section 301 prohibits the purchase, sale, or other exchange for valuable consideration of human organs for transplantation. Although the statute lists covered human organs, the Secretary is authorized to add to this list through rulemaking. ''Human organ,'' as defined by NOTA and modified by the Secretary, means ''the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, and intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.'' Adding to the definition of human organs covered by section 301 would make transfers of organs meeting the statute's requirements subject to its criminal sanctions. If, after receiving public comments, HRSA is persuaded that a change to this definition may be appropriate, HRSA may initiate rulemaking setting forth a more specific set of proposals.

Defining Vascularized Composite Allografts

To assist the Secretary in the event that he proposes, through rulemaking, to add vascularized composite allografts to the definition of organs covered by the final rule and/or to the definition of human organs governed by section 301 of NOTA, HRSA seeks feedback from stakeholders and from the public as to how such allografts should be defined. HRSA has identified two potential approaches.

Under the first approach, a regulatory definition could be broad, describing the features of the allografts without listing particular body parts. Under such an approach, the definition might extend to transplants of body parts that are not known to have been performed clinically to date, or even to body parts whose transplantation has not yet been envisioned. HRSA is interested in what elements would need to be included in such a definition in order to be broad enough to cover the universe of intended body parts, but narrow enough to put the public on notice as to which parts meet the regulatory definitions of organs. Shared characteristics that might be included in a regulatory definition could include some or all of the following: (1) A vascularized allograft containing multiple tissue types; (2) recovered from a human donor as an anatomical/structural unit; (3) transplanted into a human recipient as an anatomical/structural unit; (4) minimally manipulated, as defined by FDA in Title 21 CFR 1271.3(f); (5) for homologous use as defined by FDA in Title 21 CFR 1271.3(c); (6) not combined with another article such as a device; (7) used fresh and not cryopreserved; (8) susceptible to ischemia and, therefore, only stored temporarily (e.g., cold storage in preservation medium and intended for implantation into a recipient within hours of the recovery); and (9) susceptible to allograft rejection which requires immunosuppression that may increase infectious disease risk to the recipient. HRSA seeks feedback from the public as to whether some or all of these characteristics describe vascularized composite allografts, which would be included in the definition of organ. HRSA invites feedback on such an approach as well as the particular characteristics listed here and invites suggestions concerning the advisability of including any additional characteristics.

Under a second alternative, HRSA could propose a definition that lists specific body parts to be added to the definition of organs (e.g., face, hand, etc.). HRSA seeks feedback as to the feasibility of creating such a definition, which body parts should be included in such a definition, and whether such a definition would necessarily exclude certain body parts for which transplantation might be possible, but has not been performed to date (either in the United States or internationally).

Following this comment period and meeting, if HRSA decides to proceed with rulemaking to include vascularized composite allografts in the definition of organ, this decision will be written and published as a Notice of Proposed Rulemaking.

Dated: February 20, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–3994 Filed 2–29–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Innovations in Cancer Sample Preparation.

Date: March 20, 2008.

Time: 8 a.m. to 8 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Sherwood Githens, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116