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Draft Guidance for Industry on Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention.'' The draft guidance provides recommendations for industry for developing drugs and therapeutic biologics for the prevention and treatment of diabetes mellitus.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 In addition to the draft guidance, FDA plans to convene a public advisory committee meeting to specifically discuss new approaches for the development of products for the treatment of diabetes,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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 2, 2008.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-