The guidance describes the sensitivity and specificity of various indicators of hepatotoxic potential, as well as the observations needed to evaluate those indicators, including detection, confirmation and monitoring of liver test abnormalities, close evaluation and exclusion of other causes, and careful supportive care and follow-up to normality or return to baseline status. The guidance makes specific recommendations about the use of Hy's Law and interpretation of Hy's Law cases that are identified during clinical development and suggests research opportunities to learn more about what makes certain people more susceptible to DILI than are most persons exposed to the drug.

The guidance was issued in draft form in October 2007 for public comments. We received a total of 12 comments submitted to Docket No. 2007D–0396. FDA organized a public meeting in March 2008 for discussion of issues raised by the draft guidance and reopened the public comment period from March 6, 2008, to June 30, 2008, with Docket No. FDA–2008–D–0128 (formerly Docket No. 2007D–0396). One comment was submitted to Docket No. FDA–2008–D–0128. The comments are available at *http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/ucm071471.htm*. Presentations, discussion, and materials from the March 2008 public meeting also are available at the above Web site.

FDA considered written and verbal comments submitted to the dockets and at the public meeting before finalizing the guidance. The guidance reflects clarifying and editorial changes made in response to comments and at our own initiative.

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 premarketing evaluation of a drug's potential for causing severe DILI. 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 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 parts 312, 314, and 601 have been approved under OMB Control Numbers 0910–0014, 0910–0001, and 0910–0338, respectively.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: July 22, 2009.

Jeffrey Shuren,

Associate Comissioner for Policy and Planning.

[FR Doc. E9–18135 Filed 7–29–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2009 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a Single Source Supplement Grant to the Community Anti-Drug Coalitions of America (CADCA).

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $30,000 (total costs) for one year to the Community Anti-Drug Coalitions of America (CADCA). This is not a formal request for applications. Assistance will be provided only to the Community Anti-Drug Coalitions of America (CADCA) based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SP–09–007.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Sections 509, 516 and 520A of the Public Health Service Act, as amended.

Justification: Only the Community Anti-Drug Coalitions of America (CADCA) is eligible to apply. The Substance Abuse and Mental Health Services Administration (SAMHSA) is seeking to supplement a single source grant to the Community Anti-Drug Coalitions of America (CADCA) to support a Prevention Town Hall Meeting and a Partners Meeting at CADCA's Mid-Year Training Institute. The Training Institute will disseminate knowledge and transfer state-of-the-art information, assisting community leaders in developing effective local programs, practices, and policies that support national substance abuse goals, outcomes and efforts, such as National Alcohol and Drug Addiction Recovery Month, and prevention of underage drinking. The Prevention Town Hall Meeting will provide an in-depth overview of substance abuse prevention principles, and make the link to community-level change strategies promoted by the Drug-Free Communities grant program. The Partners Meeting is intended to bring all Federal and other key constituents together to update and discuss new initiatives and ongoing projects. Grant funds will also support evaluation of the Prevention Town Hall Meeting to obtain findings and identify directions for future trainings.

The Community Anti-Drug Coalitions of America (CADCA) is uniquely qualified to carry out the activities of this program because the purpose of the program is to partner with a national organization that has special expertise and unique broad, national-level experience in working with community anti-drug coalitions. CADCA is the only national organization that annually provides training and technical assistance through a mid-year leadership conference for thousands of members of community coalitions dedicated to preventing substance abuse. CADCA currently is the sole organization that plays a major role in helping to strengthen and develop the nation's prevention infrastructure of anti-drug coalitions in support of on-going activities funded by SAMHSA's priority grant programs including: the Substance Abuse Prevention and Treatment Block Grant, the Strategic Prevention Framework State Incentive Grant, and the Drug Free Communities Support Program. CADCA is the only identified organization that currently meets this experience level and national reach to over 5,000 identified anti-drug coalitions across the country.

Contact: Shelly Hara, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1081, Rockville, MD 20857; telephone: (240) 276–2321; E-mail: *shelly.hara@samhsa.hhs.gov*.

Dated: July 24, 2009.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health, Services Administration.

[FR Doc. E9–18187 Filed 7–29–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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

The meeting 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Immunobiology of Xenotransplantation.

Date: September 18, 2009.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, 3264, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Maryam Feili-Hariri, PhD, Scientific Review Officer, Immunology Review Branch, Scientific Review Program, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–5658, *haririmf@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 24, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–18225 Filed 7–29–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA–F Special Emphasis Panel.

Date: August 3, 2009.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Nadine Rogers, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, 301–402–2105, *rogersn2@nida.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Diversity-promoting Institutions' Drug Abuse Research Development Program.

Date: August 3, 2009.

Time: 1 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Nadine Rogers, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, 301–402–2105, *rogersn2@nida.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 23, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–18017 Filed 7–29–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 9, 2009.

Open: 8:30 a.m. to 11:45 a.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: 4:15 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, PhD, Director, Division of Extramural Activities, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Diabetes, Endocrinology, and Metabolic Diseases Subcommittee.