Dated: August 3, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–19555 Filed 8–6–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council will meet August 19, 2010, 1–3 p.m. via teleconference.

The meeting will include discussion and evaluation of grant applications reviewed by Initial Review Groups. Therefore, the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, Section 10(d).

Substantive program information, a summary of the meeting and a roster of Council members may be obtained as soon as possible after the meeting, either by accessing the SAMHSA Committee Web site at *https://nac.samhsa.gov/CSATcouncil/index.aspx,* or by contacting the CSAT National Advisory Council Designated Federal Official, Ms. Cynthia Graham (*see* contact information below).

Committee Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: August 19, 2010, 1– 3 p.m.: Closed.

Place: SAMHSA Building, 1 Choke Cherry Road, Great Falls Conference Room, Rockville, Maryland 20857.

Contact: Cynthia Graham, M.S., Designated Federal Official, SAMHSA CSAT National Advisory Council, 1 Choke Cherry Road, Room 5–1035, Rockville, Maryland 20857, Telephone: (240) 276–1692, Fax: (240) 276–1690, e-mail: *cynthia.graham@samhsa.hhs.gov.*

Dated: August 3, 2010.

Toian Vaughn,

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

[FR Doc. 2010–19539 Filed 8–6–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting 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 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 materials, 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 Advisory Council on Alcohol Abuse and Alcoholism.

Date: September 22–23, 2010.

Closed: September 22, 2010, 5:30 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Open: September 23, 2010, 9 a.m. to 3 p.m.

Agenda: Presentations and other business of the council.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Abraham P. Bautista, PhD, Executive Secretary, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20892, 301–443–9737. *bautistaa@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http:///www.silk.nih.gov/silk/niaaa1/about/roster.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: July 29, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19558 Filed 8–6–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Workshop on Optimizing Clinical Trial Design for the Development of Pediatric Cardiovascular Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) and National Institutes of Health (NIH), with support from the American Academy of Pediatrics (AAP), the American College of Cardiology (ACC), and the Society for Cardiovascular Angiography and Interventions (SCAI) are announcing a public workshop entitled "Optimizing Clinical Trial Design for the Development of Pediatric Cardiovascular Devices." The topic to be discussed is pediatric cardiovascular device development. The purpose of the public workshop is to solicit information from clinicians, academia, professional societies, other government agencies, and industry on various efficient and pragmatic clinical trial designs that are conducive to overcoming the challenges in developing devices for the pediatric cardiology market. The information gathered in this and future workshops will help to develop future guidance on optimal designs for pediatric cardiology device trials.

Date and Time: The public workshop will be held on September 30, 2010, from 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at Moscone Center, 747 Howard St., San Francisco, CA 94103.

Contact Person: Francesca Joseph, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5277, Silver Spring, MD 20903, 301–796–6805, FAX: 301–847–8621, e-mail: *francesca.joseph@fda.hhs.gov*.

Registration: Registration information will be posted on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*.

If you need special accommodations due to a disability, please contact Lynn Colegrove by phone 847–434–7820 at least 7 days in advance.

Registration and seating will be on a first-come, first-served basis. A discussion preference will be afforded to clinical research investigators involved in pediatric clinical device trials, health care givers, and patient advocates. There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited. There will be no onsite registration.

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.

SUPPLEMENTARY INFORMATION: In the medical device industry, rarely have devices been developed, evaluated, and approved specifically for treatment of children with congenital heart disease. The small, heterogeneous population, need for long-term followup, lack of market incentive, and misperceptions of regulatory requirements and costs are a few of the issues that make a standard randomized control trial difficult to conduct in pediatric cardiology. The goal of the workshop is to educate the medical device industry and pediatric clinical community about device development and regulatory approval processes, and to identify clinical trial designs that lend themselves to overcoming the challenges in pediatric cardiovascular device development. Subsequently making this information available to industry, the clinical community, and the public is imperative to furthering the development of pediatric cardiovascular devices and alleviating this critical unmet need. The marketing approval of more cardiovascular devices specifically designed and/or labeled for pediatric patients would have a significant impact on public health. Invited experts will address types of clinical trials with a particular focus on trial designs and statistical analysis methods, as well as alternative sources of clinical data, that can help to address the challenges in this particular patient population. After each section there will be an audience question and answer session and panel discussion allowing workshop participants to interact with the speakers and panelists. A concluding session will allow for additional interactions.

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

Dated: August 4, 2010.

Nancy Stade,

Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–19530 Filed 8–6–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0381]

Generic Drug User Fee; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to gather stakeholder input on the development of a generic drug user fee program. The number of human generic drug applications awaiting FDA action and the median review times for generic drug applications have increased in recent years. A user fee program could provide necessary supplemental funding, in addition to current Congressional appropriations, to allow for the timely review of such applications. Although the President's Fiscal Year (FY) 2011 budget includes generic drug user fees, new legislation would be required for FDA to establish and collect user fees under such a program. As FDA begins negotiations with the regulated industry about generic drug user fees, FDA will hold a public meeting to gather the public's input on such a program.

Date and Time: The public meeting will be held on September 17, 2010, from 9 a.m. to 5 p.m.

Location: The meeting will be held at the Hilton Washington DC/Rockville and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Persons: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6178, Silver Spring, MD 20993, 301–796–3519, FAX: 301–847–8753, e-mail: *mary.gross@fda.hhs.gov*, or Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993, 301–796–4830, FAX: 301–847–3541, e-mail: *peter.beckerman@fda.hhs.gov*.

Registration and Requests for Oral Presentations: If you wish to attend and/or present at the meeting, please register by September 9, 2010. Please e-mail your registration information to *GDUFA_Meeting@fda.hhs.gov*. Those without e-mail access may register by contacting one of the persons listed in the *Contact Persons* section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail address, and phone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants, based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak, and if the entire meeting time is not needed for presentations, FDA reserves the right to terminate the meeting early.

If you need special accommodations due to a disability, please contact Mary Gross or Peter Beckerman (see *Contact Persons*) at least 7 days before the meeting.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments by October 17, 2010. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.,