

report will be available on FDA's Web site at a later date.

FOR FURTHER INFORMATION CONTACT:

Carolyn Staples, Office of Planning (HFP-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5274, or William Hagan, Office of Planning (HFP-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-8816.

SUPPLEMENTARY INFORMATION:

I. Background

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes PDUFA III. In conjunction with the passage of PDUFA III, FDA agreed to certain performance goals and procedures that were described in an enclosure to a June 4, 2002, letter from the Secretary of Health and Human Services, Tommy Thompson, to Congress entitled "PDUFA Reauthorization Performance Goals and Procedures" (PDUFA Goals and Procedures).

One of the goals relates to FDA's performance of first cycle reviews of original NMEs for NDAs and BLAs (PDUFA Goals and Procedures, section 10). Related to this goal, FDA was to retain an independent expert consultant to undertake a study to evaluate issues associated with the agency's conduct of first cycle reviews. The study was to assess the following objectives: (1) Current first cycle review performance and any changes that occur after FDA publishes guidance on Good Review Management Principles (GRMPs), (2) the first cycle review history of all NDAs for new molecular entities and all BLAs during PDUFA III, and (3) the effectiveness of FDA's staff training regarding GRMPs. FDA awarded a contract to an independent expert to study these issues. The report referred to in this document covers the retrospective portion of objectives (1) and (2) listed previously.

In accordance with the PDUFA goal, the report is being made available to the public.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the SAMHSA Center for Substance Abuse Prevention (CSAP) National Advisory Council on February 14, 2006.

The meeting will be open and will include a Director's Report; discussions related to National Outcome Measures; an update on SAMHSA's Drug Free Communities programs; and a panel presentation on the roles of Project Officers, Grants Management staff and Contracts Management staff.

A roster of Council members may be obtained either by accessing the SAMHSA Council Web site, <http://www.samhsa.gov/council/csap/csapnac.aspx> or by communicating with the contact listed below. Substantive program information, a summary of the meeting, and the transcript for the open session will also be available on the SAMHSA CSAP Council Web site as soon as possible after the meeting. Attendance by the public will be limited to space available.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council.

Date/Time: Tuesday, February 14, 2006, 12 p.m. to 5 p.m.

Place: Washington DC Convention Center, 801 Mount Vernon Place, NW., Room 204 B, Washington, DC 20001.

Type: Open.

Contact: Tia Haynes, Committee Management Specialist, 1 Choke Cherry Road, Room 4-1066, Rockville, Maryland 20857. *Telephone:* (240) 276-2436. *Fax:* (240) 276-2430 *E-mail:* Tia.haynes@samhsa.hhs.gov.

Dated: February 1, 2006.

Toian Vaughn,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2006-23795]

Towing Safety Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Towing Safety Advisory Committee (TSAC). TSAC advises the Coast Guard on matters relating to shallow-draft inland and coastal waterway navigation and towing safety.

DATES: Application forms should reach us on or before April 30, 2006.

ADDRESSES: You may request an application form by writing to Commandant (G-PSO-1); U.S. Coast Guard, Room 1210; 2100 Second Street, SW., Washington, DC 20593-0001; by calling 202-267-0214; or by faxing 202-267-4570. Send your original completed and signed application in written form to the above street address. Be sure to sign and include the short page that allows us to keep political affiliation on file. This notice is available on the Internet at <http://dms.dot.gov> in docket USCG-2006-23795 and the application form is also available at <http://www.uscg.mil/hq/g-m/advisory/index.htm>. (Click on "ACM Application".)

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Miente; Assistant Executive Director of TSAC, telephone 202-267-0214, fax 202-267-4570, or e-mail gmiente@comdt.uscg.mil.

SUPPLEMENTARY INFORMATION: The Towing Safety Advisory Committee (TSAC) is a Federal advisory committee mandated by Congress and operates under 5 U.S.C. App. 2, (Pub. L. 92-463, 86 Stat. 770, as amended). It advises the Secretary of Homeland Security on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. This advice also assists the Coast Guard in formulating the position of the United States in advance of meetings of the International Maritime Organization.

TSAC meets at least once a year at Coast Guard Headquarters, Washington, DC, or another location selected by the Coast Guard. It may also meet for extraordinary purposes. Its working groups may meet to consider specific issues as required. The 16-person membership includes 7 representatives of the Barge and Towing Industry (reflecting a regional geographical balance); 1 member from the Offshore Mineral and Oil Supply Vessel Industry; and 2 members from each of the following areas: Maritime Labor; Shippers (of whom at least one shall be engaged in the shipment of oil or hazardous materials by barge); Port Districts, Authorities, or Terminal Operators; and the General Public.