

public about that topic. FDA uses the feedback provided by the public to update this resource.

Phase II is the subject of this document and is described in more detail in section II of this document.

Phase III of the Transparency Initiative will address ways FDA can become more transparent to regulated industry, to foster a more efficient and cost-effective regulatory process. The Task Force solicited comments from the public on this topic in March 2010 (75 FR 11893, March 12, 2010) and draft proposals from this phase are expected in the summer of 2010.

## II. Phase II: Public Disclosure

The second phase of the Transparency Initiative relates to FDA's policies on disclosure of information to the public about FDA activities. FDA is releasing a report that contains 21 draft proposals that we are issuing for public comment. The draft proposals, along with background material, can be found on the FDA Web site at [www.fda.gov/transparency](http://www.fda.gov/transparency). FDA is accepting comments from the public on the draft proposals on the FDA Web site as well as through the docket (see section III of this notice).

The Task Force solicited comments from the public about information FDA should provide to the public about what FDA is doing, the bases for the agency's decisions, and the processes used to make agency decisions. The Task Force reviewed and considered all the comments received from a range of stakeholders. The Task Force also identified on its own initiative ways to improve transparency that are reflected in the report.

In the report, the Task Force makes available for public comment 21 draft proposals for changes in policy related to the disclosure of information FDA has in its possession, while supporting the redaction of trade secrets and individually identifiable patient information from all documents proposed for disclosure. Other topics on which FDA plans to make changes or on which the Task Force is not proposing policy changes at this time are discussed in the "Other Areas of Public Comment" section of the report.

After considering public comment on the draft proposals, the Task Force will recommend specific proposals to the Commissioner for consideration, and then FDA will announce which of the proposals it will implement, and the projected timeframe for implementation. Some of the draft proposals may require extensive resources to implement, and some may require changes to regulations or legislation. Therefore, in addition to

input on the content of the proposals and whether the Task Force has struck the right balance with respect to the draft proposals, FDA is seeking input on how the agency should prioritize the proposals, if it decided to implement them. The Task Force will consider feasibility and priority, considering other agency priorities that require resources, when developing its specific recommendations for the Commissioner.

## III. Request for Comments

FDA is interested in receiving comments from the public about the content of the draft proposals as well as on which draft proposals should be given priority. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify the draft proposal which your comment addresses by the number assigned to that proposal. 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., Monday through Friday. Comments can also be submitted on each draft proposal via the FDA Web site, [www.fda.gov/transparency](http://www.fda.gov/transparency).

Dated: May 17, 2010.

**Leslie Kux,**

*Acting 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 that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) National Advisory Council will meet on June 9, 2010 from 1 p.m. to 4 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 Committee members may be obtained either by accessing the SAMHSA Committee's Web site at <https://www.samhsa.gov/council/csap/csapnac.aspx> as soon as possible after the meeting, or by contacting CSAP National Advisory Council's Designated Federal Official, Ms. Tia Haynes (see contact information below).

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

*Date/Time/Type:* June 9, 2010, 1 p.m. to 4 p.m.: Closed.

*Place:* 1 Choke Cherry Road, Conference Room 4-1058, Rockville, Maryland 20857.

*Contact:* Tia Haynes, Designated Federal Official, SAMHSA/CSAP National Advisory Council, 1 Choke Cherry Road, Room 4-1066, Rockville, MD 20857, Telephone: (240) 276-2436; FAX: (240) 276-2430. E-mail: [tia.haynes@samhsa.hhs.gov](mailto:tia.haynes@samhsa.hhs.gov).

**Toian Vaughn,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Brain Function and Structure.

*Date:* June 8, 2010.

*Time:* 9 a.m. to 9 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Kevin Walton, PhD, Scientific Review Officer, Center for