DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: As part of the second phase of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled “FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration.” The report includes 21 draft proposals about expanding disclosure of information by the agency while maintaining confidentiality of trade secrets and individually identifiable patient information. FDA is seeking public comment on the draft proposals, as well as on which draft proposals should be given priority. Some of the draft proposals may require extensive resources to implement, and some may require changes to regulations or legislation.

DATES: Submit either electronic or written comments by July 20, 2010.

ADDRESSES: Submit electronic comments to http://www.regulations.gov or on the FDA Web site, www.fda.gov/transparency. Submit written comments to the Division of Dockets Management (HFA–2–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets at the heading of this document.

FOR FURTHER INFORMATION CONTACT: Afia Asamoah, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 1, rm. 2220, Silver Spring, MD 20993, 301–796–4625, FAX: 301–847–3531, e-mail: Afia.Asamoah@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Every day, the U.S. Food and Drug Administration (FDA) makes important health and safety decisions about foods, drugs, medical devices, cosmetics, and other widely used consumer products. Transparency in FDA’s activities and decisionmaking allows the public to better understand the agency’s decisions, increasing credibility and promoting accountability. Transparency helps the agency to more effectively protect and promote the public health.

In January 2009, President Obama issued a memorandum on Transparency and Open Government calling for an “unprecedented level of openness in Government” and directing the Director of the Office of Management and Budget (OMB) to issue an Open Government Directive instructing executive departments and agencies to take specific actions to implement the principles of transparent, collaborative, and participatory government. The Open Government Directive was issued in December. Under the leadership of Secretary Kathleen Sebelius, the U.S. Department of Health and Human Services has also prioritized transparency and openness. In June 2009, FDA Commissioner Dr. Margaret Hamburg launched FDA’s Transparency Initiative to implement these efforts at FDA.

The initiative is overseen by a Task Force representing key leaders of FDA. The internal task force is chaired by the Principal Deputy Commissioner of the FDA and includes five of the agency’s center directors, the Chief Counsel, the Associate Commissioner of Regulatory Affairs, and the Chief Scientist. The Task Force is charged with submitting a written report to the Commissioner on the Task Force’s findings and recommendations.

Over the last 11 months, the Task Force has held two public meetings, launched an online blog (http://fdatransparencyblog.fda.gov/), and opened a docket. The online blog and the docket have received over 1,500 comments.

The Task Force is proceeding with the Transparency Initiative in three phases:

• Phase I: FDA Basics
• Phase II: Public Disclosure
• Phase III: Transparency to Regulated Industry

Phase I is intended to provide the public with basic information about FDA and how the agency does its work. This phase was unveiled in early January 2010 with the launch of a web-based resource called FDA Basics (www.fda.gov/fdadbasics). The resource now includes (1) 126 questions and answers about FDA and the products that the agency regulates, (2) 9 short videos that explain various FDA activities, and (3) 10 conversations with FDA officials about the work of their Offices. Each month, senior officials from FDA product centers and offices host online sessions about a specific topic and answer questions from the
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. 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 responses 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.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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 or 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.

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

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