

Dated: May 13, 2010.

**Maryam I. Daneshvar,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Conducting Public Health Research in Kenya (U01)(Panel A), Funding Opportunity Announcement (FOA) GH10-003, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

**TIME AND DATE:** 1 p.m.–5 p.m., June 29, 2010 (Closed).

**PLACE:** Teleconference.

**STATUS:** The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

**MATTERS TO BE DISCUSSED:** The meeting will include the initial review, discussion, and evaluation of applications received in response to “Conducting Public Health Research in Kenya (U01)(Panel A),” FOA GH10-003.

**CONTACT PERSON FOR MORE INFORMATION:** Susan Stanton, D.D.S., Scientific Review Officer, CDC, 1600 Clifton Road, NE., Mailstop D74, Atlanta, GA 30333, Telephone: (404) 639-4640.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 6, 2010.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0247]

#### 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](http://www.fda.gov/transparency). Submit written comments to the Division of Dockets Management (HFA-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](mailto: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/fdabasics](http://www.fda.gov/fdabasics)). 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