DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to particpate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for ''The Building Research Infrastructure Capacity'' (BRIC) RFA, are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: The Building Research Infrastructure Capacity (BRIC) RFA.

Date: December 15–16, 2005 (Open on December 15 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

Place: Doubletree Hotel, Executive Meeting Center, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: November 21, 2005.

Carolyn M. Clancy,

Director.

[FR Doc. 05–23491 Filed 11–29–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004G–0381]

Guidance for Industry and Food and Drug Administration Staff, Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Guidance for Industry and FDA Staff entitled ''Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The document finalizes the draft guidance entitled ''Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The guidance clarifies the circumstances under which FDA may access and copy records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (''Bioterrorism Act''), and describes the procedure that FDA intends to follow to exercise its authority to inspect records under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written or electronic comments on agency guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. Submit written comments on the final guidance to the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Diane Kelley, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6860, or e-mail *Diane.Kelley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 9, 2004 (69 FR 71657), FDA (we) announced the availability of a draft guidance entitled ''Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' FDA has finalized the guidance.

FDA received a number of comments in response to the draft guidance. The agency considered those within the scope of this document carefully and is making two changes to the draft guidance. First, we have expanded the answer to question III.C, which describes records FDA may not access, to clarify that FDA has authority to access lists of ingredients (sections 414(a) and 704(a) of the act. Second, we have changed the answer to question III. E, which describes how FDA intends to make a records request, to indicate that FDA intends to use a new form to make such a request. FDA has decided to create a specific form to document a request to access and copy records under the Bioterrorism Act. The form FDA 482c ''Notice of Inspection—Request for Records'' will be presented to the owner, operator, or agent in charge, once FDA determines that the threshold for requesting records has been attained. This form will assist industry and the agency in distinguishing this type of notice from a routine Notice of Inspection.

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on how it will exercise its authority to access records under the Bioterrorism Act (sections 414(a) and 704(a) of the act (21 U.S.C. 350c and 374)). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork