240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 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: Abigail C. Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6484, Silver Spring, MD 20993–0002, 301–796–0174.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Safety Evaluation of Drug or Biologic Combinations.'' This guidance provides recommendations on nonclinical approaches to support the clinical study and approval of FDCs, co-packaged products, and some adjunctive therapies. The intent of this guidance is to delineate general guiding principles.

In the **Federal Register** of January 26, 2005 (70 FR 3714), FDA announced the availability of a draft guidance entitled ''Nonclinical Safety Evaluation of Drug Combinations.'' This notice gave interested persons an opportunity to submit comments. As a result of the comments, certain sections of this guidance have been reworded to improve clarity. Additionally, the following revisions have been made to the guidance: (1) The inclusion of combinations of biologics regulated by the Center for Drug Evaluation and Research and drugs, (2) a narrowing of the description of ''adjunctive therapies'' covered by the guidance, and (3) a clarification of the aspects of the developmental reproductive toxicology sections.

This 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 nonclinical safety evaluation of drug and biologic combinations. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3713 Filed 3–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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: National Cancer Institute Initial Review Group, Subcommittee E—Cancer Epidemiology, Prevention & Control.

Date: April 9–10, 2006.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Hasnaa Shafik, MD, PhD., Scientific Review Administration, Division of Extramural Activities, RPRB, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd., Room 8037, Bethesda, MD 20892, (301) 451–4757, *shafikh@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 8, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–2523 Filed 3–14–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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: National Center for Research Resources Special Emphasis Panel, Isel Cell Resource SEP.

Date: March 30–31, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Mohan Viswanathan, PhD., Deputy Director, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892–4874, 301–435–0829, *mv10f@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure; 93.306, 93.333, National Institutes of Health, HHS)