(NDA 21–060) was initially submitted on December 28, 1999.

3. *The date the application was approved*: December 28, 2004. FDA has verified the applicant's claim that NDA 21–060 was approved on December 28, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,228 days (U.S. Patent No. 5,795,864) and 5 years (U.S. Patent No. 5,364,842) of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 15, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 11, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions are to be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–3712 Filed 3–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration Science Board (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the Science Board provides advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading it's scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on March 31, 2006, from 8 a.m. to 4 p.m.

Location: Food and Drug Administration, rm. 1066, 5630 Fishers Lane, Rockville, MD 20857.

Contact Person: Jan Johannessen, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, *Jan.Johannessen@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Science Board will conclude their discussion on drug safety from the meeting of November 4, 2005, and will hear about and discuss a request by the agency for a review of the agency's science programs. The Science Board will then hear about and discuss the agency's response to the recommendations contained in the Science Board's peer review of the Office of Regulatory Affairs Pesticide Program, plans for a Science Board peer review of the Center for Veterinary Medicine's intramural portion of the National Antimicrobial Resistance Monitoring System, and the science priorities of the agency's Office of Women's Health.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 24, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 24, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jan Johannessen (see *Contact Person*) at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 7, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–3639 Filed 3–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0004]

Guidance for Industry on Nonclinical Safety Evaluation of Drug or Biologic Combinations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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 fixed-dose combination products (FDCs), co-packaged products, and some adjunctive therapies.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–

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)