the Federal Advisory Committee Act (FACA), section 10(d) of 5 U.S.C., Appendix 2, implementing regulations, and procurement regulations, 41 CFR 101–6.1023 and 48 CFR 315.604(d). The discussions at this meeting of contract proposals submitted in response to the above-referenced RFP are likely to reveal proprietary information and personal information concerning individuals associated with the proposals. Such information is exempt from disclosure under the above-cited FACA provision and procurement rules that protect the free exchange of candid views and facilitate Department and Committee operations.

Name of TRC: The Agency for Healthcare Research and Quality-''Communications Support''.

Date: August 18, 2003 (Closed to the public).

Place: Agency for Healthcare Research & Quality, 540 Gaither Road, Conference Room 1, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain information regarding this meeting should contact Kevin Murray, Office of Communications and Knowledge Transfer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850, 301–427–1853.

Dated: July 23, 2003

Carolyn M. Clancy,

Director.

[FR Doc. 03–19539 Filed 7–30–03; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Evaluation of Web-Based HIV Risk Behavior Surveillance Among Men Who Have Sex With Men, Program Announcement Number 03095

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 following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Evaluation of Web-Based HIV Risk Behavior Surveillance Among Men Who Have Sex With Men, Program Announcement Number 03095.

Times and Dates: 7 p.m.–8 p.m., August 20, 2003 (Open), 8 a.m.–08:30 a.m., August 21, 2003 (Open), 8:30 a.m.–5 p.m., August 21, 2003 (Closed).

Place: The Westin Atlanta Airport Hotel, 4736 Best Road, Atlanta, GA 30337, Telephone 404.762.7676.

Status: Portions of 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 review, discussion, and evaluation of applications received in response to Program Announcement Number 03095.

Contact Person for More Information: Beth Wolfe, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, 1600 Clifton Road, NE, MS–E07, Atlanta, GA 30333, Telephone 404.639.8531.

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: July 23, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–19480 Filed 7–30–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF/HS–2003–15]

Fiscal Year 2003 Discretionary Announcement for Head Start Partnerships With Historically Black Colleges and Universities; Availability of Funds and Requests for Applications; Corrections

AGENCY: Administration for Children and Families (ACF), HHS.

ACTION: Correction Notice for Head Start Historically Black Colleges and Universities Program Announcement No. ACYF/HHS–2003–15

SUMMARY: The is a correction notice for the Head Start Historically Black Colleges and Universities funding notice FR Doc 03–18165 that was published on July 21, 2003 (68 FR 43113). The document contained incorrect due dates for receipt of applications.

FOR FURTHER INFORMATION CONTACT: The Head Start Discretionary Grant Support Team (1–800–351–2293) is available to answer questions concerning application requirements and to refer you to the appropriate contact person in ACYF for programmatic questions. You may e-mail your questions to : *HSB@esilsg.org.* When contacting ACYF directly with programmatic questions please send to William F. Wilson, Grants Officer 330 C Street, SW., Washington, DC 20447, (202) 205–8913, *wwilson@acf.hhs.gov.* In order necessary, if you plan to submit an application you are requested to send a post card or call with the following information: the name, address, telephone and fax numbers, and e-mail addresses of the college/university at least four weeks prior to the submission deadline date to: ACYF Operations Center, Historically Black Colleges and Universities, 1150 Connecticut Avenue, NW., Suite 1100, Washington DC 20036, Telephone: 1–800–351–2293, e-mail: *HSB@esilsg.org.* An application kit including the necessary application forms and appendices can be obtained by contacting the above address, and/or visiting the ACYF Web site at: *http://www.acf.hhs.gov/programs/hsb/grant/fundingopportunities/fundopport.htm.*

Correction: In the **Federal Register** of July 21, 2003 in FR Doc 03–18165, on page 43119 the due date for receipt of applications is August 20, 2003. Please use this deadline date for submissions of applications for funding opportunities available for the FY '03 Head Start Historically Black Colleges and Universities program.

Dated: July 25, 2003.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 03–19456 Filed 7–23–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E–0339]

Determination of Regulatory Review Period for Purposes of Patent Extension; BENICAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BENICAR and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions 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*.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product BENICAR (olmesartan medocomil). BENICAR is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BENICAR (U.S. Patent No. 5,616,599) from Sankyo Company, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 30, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BENICAR represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for BENICAR is 2,522 days. Of this time, 1,882 days occurred during the testing phase of the regulatory review period, while 640 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355)(i) became effective*: June 1, 1995. The applicant claims May 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 1, 1995, which was 30 days after FDA receipt of the IND.

2. T*he date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: July 25, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for BENICAR (NDA 21–286) was initially submitted on July 25, 2000.

3. *The date the application was approved*: April 25, 2002. FDA has verified the applicant's claim that NDA 21–286 was approved on April 25, 2002.

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 application for patent extension, this applicant seeks 756 days 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 September 29, 2003. 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 January 27, 2004. 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 should 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. Comment 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: July 14, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–19446 Filed 7–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0294]

Anesthetic and Life Support Drugs Advisory Committee; 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: Anesthetic and Life Support Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 9 and 10, 2003, from 8 a.m. to 5 p.m. Interested persons and organizations may submit written or electronic comments until October 10, 2003, to the Division of Dockets Management (*see* **ADDRESSES**).

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments.* Select ''2003N–0294—Opiate Risk Management'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm.