J. Where to Obtain Additional Information

To receive additional written information, call 1–888–472–6874. You will be asked to leave your name, address, and phone number, and refer to Announcement Number 98023. You will receive a complete program announcement. CDC will not send application kits by facsimile or express mail unless the cost for the latter is paid by the addressee.

This and other CDC announcements are also available through the CDC homepage on the Internet. The address for the CDC homepage is http://www.cdc.gov.

Business management technical assistance may be obtained from Juanita Dangerfield, Grants Management Specialist, Grants Management Branch, Centers for Disease Control and Prevention (CDC), Procurement and Grants Office, 255 East Paces Ferry Road NE., Room 300, Mailstop E–15, Atlanta, GA 30305, telephone (404) 842–6577, or facsimile at (404) 842–6513, or INTERNET address: jdd2@cdc.gov.

Programmatic technical assistance may be obtained from the National Center for HIV, STDs and TB Prevention, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30303, for HIV, contact Carol Aloisio, telephone (404) 639–0902; for STD, contact Sevgi Aral, telephone (404) 639–8259; for TB, contact Bess Miller, telephone (404) 639–8120.

Please refer to Announcement 98023 when requesting information and submitting an application.

Dated: April 9, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–9909 Filed 4–14–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Infectious Diseases: Meeting

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 committee meeting.

Name: Board of Scientific Counselors, National Center for Infectious Diseases (NCID).

Times and Dates: 10 a.m.–5:30 p.m., April 30, 1998. 8:30 a.m.–2:30 p.m., May 1, 1998.

Place: CDC, Auditorium B, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Board of Scientific Counselors, NCID, provides advice and guidance to the Director, CDC, and Director, NCID, in the following areas: program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

Matters To Be Discussed: Agenda items will include:

1. NCID Update
2. Program Updates:
   - Division of Quarantine
   - Division of Viral and Rickettsial Diseases
   - Division of Bacterial and Mycotic Diseases
   - Division of AIDS, Tuberculosis, and STD Laboratory Research
3. Emerging Infectious Disease Plan—Update
4. Core Capabilities for Public Health Laboratories
5. Update: Rift Valley Fever
6. Scientific Updates: Late Breakers
7. Discussion and Recommendations

Other agenda items include announcements/introductions; follow-up on actions recommended by the Board in December 1997; and consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Diane S. Holley, Office of the Director, NCID, CDC, Mailstop C–20, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0078.

Dated: April 8, 1998.

Nancy C. Hirsch,

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

[FR Doc. 98–9910 Filed 4–14–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA 93.600 Head Start, Head Start Act as Amended]

Fiscal Year 1998 Discretionary Announcement for Head Start Partnerships With Historically Black Colleges and Universities

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Notice of announcement of the availability of funds and request for applications for training grants for Historically Black Colleges and Universities in Partnership with Head Start and Early Head Start Grantees.

SUMMARY: The Administration for Children and Families, Administration on Children, Youth and Families announces the availability of funds for Head Start Training Partnerships with Historically Black Colleges and Universities. The purpose is to utilize the capabilities of these institutions of higher education to improve the quality and long-term effectiveness of Head Start and Early Head Start by developing models of academic training and forming partnerships between the HBCUs and Head Start and Early Head Start.

DATES: The closing date for receipt of applications is 5:00 p.m. EST June 15, 1998.

ADDRESSES: Applications, including all necessary forms can be downloaded from the Head Start web site at: www.acf.dhhs.gov/programs/hsb.

Hard copies of the program announcement and application kit may be obtained by writing or calling: Head Start Partnerships with Historically Black Colleges and Universities (HBCUs), Administration on Children, Youth and Families Operations Center, 1225 Jefferson Davis Highway, Suite 415, Arlington, VA 22202. The telephone number is 1–800–351–2293.

FOR FURTHER INFORMATION: Same address and telephone number as indicated under addresses above.

Eligible Applicants: Historically Black Colleges and Universities as defined in Executive Order 12677 which offer courses of study in the areas of human services delivery, early childhood education and care, health care services, community development and/or human resource development. Current grantees are not eligible to apply for this wave of applications.

Project Duration: Awards, on a competitive basis will be for a one-year budget period; project periods will be for four years.

Federal Share of Project Costs: The maximum Federal share for each project is not to exceed $125,000 per year. The annual budget should include the cost for two staff members to attend a conference in the Washington, DC area. Although there are no matching requirements, applicants are encouraged to provide non-Federal contributions to the project.

Estimated Number of Projects To Be Funded: It is anticipated that up to five projects will be funded.

Statutory Authority: The Head Start Act, as amended, 42 U.S.C. 9801 *et seq.*

Dated: April 7, 1998.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 98–9941 Filed 4–14–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0144]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZAGAM®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZAGAM® 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 Commissioner 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 ZAGAM® (sparfloxacin). ZAGAM® is indicated for community-acquired pneumonia and acute bacterial exacerbations of chronic bronchitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZAGAM® (U.S. Patent No. 4,795,751) from Dainippon Pharmaceutical Co., 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 May 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZAGAM® 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 ZAGAM® is 2,030 days. Of this time, 1,671 days occurred during the testing phase of the regulatory review period, while 359 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) became effective:* June 1, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 1, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act:* December 27, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for ZAGAM® (NDA 20–677) was initially submitted on December 27, 1995.

3. *The date the application was approved:* December 19, 1996. FDA has verified the applicant's claim that NDA 20–677 was approved on December 19, 1996.

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 1,194 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 15, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 13, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–9864 Filed 4–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee Meeting; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is cancelling the meeting of the Pulmonary-Allergy Drugs Advisory Committee scheduled for April 20, 1998. The meeting was announced in the **Federal Register** of March 19, 1998 (63 FR 13413).

FOR FURTHER INFORMATION CONTACT: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21),