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),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545.

Dated: April 8, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–9866 Filed 4–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of AIDS Research, Office of the Director; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Office of AIDS Research Advisory Council on April 29, 1998, National Institutes of Health, Building 31, C Wing, Conference Room 6, 9000 Rockville Pike, Bethesda, Maryland 20892.

The meeting will be open to the public from 9:00 a.m. until adjournment. Attendance by the public will be limited to space available. The purpose of the meeting will be to review and obtain the Council's advice on the following agenda items: (1) a report of the Acting Director, OAR; (2) a review of the FY 2000 NIH Plan for HIV-Related Research; (3) updates from the AIDS Vaccine Research Committee, the Prevention Science Working Group, and the Therapeutics Research Working Group; and (4) an overview of international NIH AIDS research programs.

Copies of the meeting agenda and roster of council members will be furnish upon request by Ms. Deborah Kraut, Program Analyst, Office of AIDS Research (OAR), 9000 Rockville Pike, Building 31, Room 4B62, National Institutes of Health, Bethesda, Maryland, Telephone (301) 402–8655 and Dr. Robert W. Eisinger, Head, Science Policy and Analysis Section, OAR, Telephone (301) 402–8655 will provide substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Kraut no later than April 22, 1998.

Dated: April 9, 1998.

LaVerne Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–9984 Filed 4–14–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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:

Purpose/Agenda: To review and evaluate contract proposals.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date of Meeting: April 15, 1998 (Telephone Conference).

Time: 11:00 a.m.

Place of Meeting: Willco Building, 6000 Executive Boulevard, Suite 400, Rockville, MD 20892–7003.

Contact Person: Sean O'Rourke, 6000 Executive Boulevard, Suite 409, Rockville, MD 20892–7003, 301–443–2861.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance, Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; and 93.891, Alcohol Research Center Grants; National Institutes of Health)

Dated: April 9, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–9992 Filed 4–14–98; 8:45 am]

BILLING CODE 4140–01–M

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 National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Phase II Study of Arsenic Trioxide in Leukemia Telephone Conference Call.

Date: April 27, 1998.

Time: 12:30 p.m. to Adjournment.

Place: National Cancer Institute, Executive Plaza North, Room 635C, 6130 Executive Boulevard, Bethesda, MD 20892.

Contact Person: David Irwin, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 635C, 6130 Executive Boulevard, MSC 7408, Bethesda, MD 20892–7408, Telephone: 301/402–0371.

Purpose/Agenda: To review, discuss and evaluate grant applications.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 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)

Dated: April 9, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–9983 Filed 4–14–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to Section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a teleconference meeting of the Advisory Committee to the Director, National Cancer Institute.

The entire meeting will be open to the public as indicated below, with attendance by the public limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Linda Quick-Cameron, Committee Management Officer, National Cancer Institute, Executive Plaza North, Room 609, 6130 Executive Blvd., MSC 7410, Bethesda, MD 20892–7410 (301/496–5708). A summary of the