

requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

We have not prepared a Regulatory Impact Analysis for this notice, in accordance with Executive Order 12866, because it will not have a significant economic impact, nor does it impose any unfunded mandates on State, local, or tribal governments or the private sector. Furthermore, we certify that the notice will not have a significant impact on a substantial number of small entities or small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

#### **X. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Authority:** Sections 1816(f), 1834(a)(12), and 1842(b) of the Social Security Act (42 U.S.C. 1395h(f), 1395m(a)(12), and 1395u(b)). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 6, 2002.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 03-4087 Filed 2-27-03; 8:45 am]

**BILLING CODE 4120-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 02E-0020]

#### **Determination of Regulatory Review Period for Purposes of Patent Extension; ZOMETA**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ZOMETA 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 Dockets Management Branch (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 ZOMETA (zoledronic acid). ZOMETA is indicated for the treatment of hypercalcemia of malignancy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZOMETA (U.S. Patent No. 4,939,130) from Novartis Corp., and the Patent and Trademark Office

requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 14, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZOMETA 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 ZOMETA is 2,810 days. Of this time, 2,201 days occurred during the testing phase of the regulatory review period, while 609 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 (the act) (21 U.S.C. 355) became effective:* December 12, 1993. The applicant claims September 18, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 12, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* December 21, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for ZOMETA (NDA 21-223) was initially submitted on December 21, 1999.

3. *The date the application was approved:* August 20, 2001. FDA has verified the applicant's claim that NDA 21-223 was approved on August 20, 2001.

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 1,752 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 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 August 27, 2003. 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. Three copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2003.

**Jane A. Axelrad,**

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

[FR Doc. 03–4691 Filed 2–27–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting.

*Name:* Advisory Committee on Infant Mortality (ACIM).

*Date and Time:* March 26, 2003; 9 a.m.–5 p.m., March 27, 2003; 8:30 a.m.–3 p.m.

*Place:* The Latham Hotel, 3000 M Street, NW., Washington, DC 20007, (202) 726–5000.

*Status:* The meeting will be open to the public.

*Purpose:* The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs which are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; factors determining the length of hospital stay following childbirth; strategies to coordinate the variety of Federal, State, and local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start initiative and infant mortality objectives from *Healthy People 2010*.

*Agenda:* Topics that will be discussed include the following: Low-Birth Weight; Disparities in Infant Mortality; and the Healthy Start Program. Agenda items are subject to change as priorities are further determined.

*For Further Information Contact:* Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM,

Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443–2170.

Individuals who are interested in attending any portion of the meeting or who have questions regarding the meeting should contact Ann M. Koontz, C.N.M., Dr. P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443–6327.

Dated: February 24, 2003.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 03–4805 Filed 2–27–03; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; 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 meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Office of AIDS Research Advisory Council.

*Date:* April 9–10, 2003.

*Time:* 9 a.m. to 12 p.m.

*Agenda:* A Report of the Director addressing OAR initiatives. The topic of the meeting will be “HIV and HCV Infection.”

*Place:* National Institutes of Health, Building 31C, Conference Room 6C10, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Jack Whitescarver, Director, Office of AIDS Research, OD, National Institutes of Health, 9000 Rockville Pike, Building 2, Room 4E14, Bethesda, MD 20892, (301) 496–0357.

Information is also available on the Institute's/Center's home page: <http://www.nih.gov/od/oar/index.htm>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency

Syndrome Research Loan Repayment Program, National Institute of Health, HHS)

Dated: February 20, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–4660 Filed 2–27–03; 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 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel, SBIR Topic 181: Clinical Trials Data Collection Using Hand-Held Technology.

*Date:* March 19–20, 2003.

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

*Agenda:* To review and evaluate contract proposals.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review & Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8057, MSC 8329, Bethesda, MD 20892–8329, (301) 496–7421, [kerwinm@mail.nih.gov](mailto:kerwinm@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: February 20, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–4665 Filed 2–27–03; 8:45 am]

**BILLING CODE 4140–01–M**