DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1237]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RELENZA 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 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 V. Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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 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 RELENZA (zanamivir). RELENZA is indicated for the treatment of uncomplicated acute illness due to influenza virus in adults and adolescents twelve years and older who have been symptomatic for no more than two days. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for RELENZA (U.S. Patent No. 5,360,817) from Glaxo Wellcome, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 13, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of RELENZA 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 RELENZA is 1,800 days. Of this time, 1,527 days occurred during the testing phase of the regulatory review period, while 273 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*: August 23, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 23, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: October 27, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for RELENZA (NDA 21–036) was initially submitted on October 27, 1998.

3. *The date the application was approved*: July 26, 1999. FDA has verified the applicant's claim that NDA 21–036 was approved on July 26, 1999.

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 1,001 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by April 29, 2002. 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 26, 2002. 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 24, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–4596 Filed 2–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds HRSA Competitive Grants Notice: Cancellation for the Public Health Training Centers Grant Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Cancellation of notice of availability of funds.

SUMMARY: This notice rescinds the Notice of Availability of Funds for the Public Health Training Centers Grant Program (93.249) published on Tuesday, January 29, 2002 (67 FR 4263). That notice announced the availability of funds for fiscal year (FY) 2002 competitive grant programs that were not included in the *HRSA Preview*. Based on FY 2002 funding, there are

insufficient funds available for new public health training centers projects.

FOR FURTHER INFORMATION CONTACT: Mark Wheeler, Grants Management, Bureau of Health Professions, Parklawn Building, Room 8c–26, 5600 Fishers Lane, Rockville, Maryland 20857 (301) 443–6880 (*mwheeler@hrsa.gov*).

Dated: February 20, 2002.

Elizabeth M. Duke,

Acting Administrator.

[FR Doc. 02–4597 Filed 2–26–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of April 2002.

Name: Advisory Committee on Infant Mortality (ACIM).

Date and Time: April 15, 2002; 9:00 a.m.–5:00 p.m., April 16, 2002; 8:30 a.m.–3:00 p.m.

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

The meeting is 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: Early Postpartum Discharge; Low-Birth Weight; Disparities in Infant Mortality; and the Healthy Start Program.

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 Ms. Kerry P. Nesseler, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–2170.

Agenda items are subject to change as priorities are further determined.

Dated: February 21, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–4598 Filed 2–26–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: December 2001

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of December 2001, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.,* a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
Program-Related Convictions	
BEP Services, LP Louisville, KY	08/15/2001
Filkins, Ann Weaver Pulteney, NY	01/20/2002
Jimenez-Casso, Jose Bayamon, PR	01/20/2002
Johnson, Eddie Dillon, SC	01/20/2002
Katz, Ronald New York, NY	01/20/2002
Lopez-Morales, Angel Bayamon, PR	01/20/2002
Richey, Donna Marie E Wenatchee, WA	01/20/2002
Roche, Fernando M Miami, FL	01/20/2002
Temple, Terry Lee Scottsdale, AZ	01/20/2002
Thomas, Cynthia Wichita, KS	01/20/2002
Tirado-Rivera, Hernon Bayamon, PR	01/20/2002
Felony Conviction for Health Care	
Dilli, Darlene Marie McPherson, KS	0120/02
Felony Control Substance Conviction	
Gimenez, Alonzo R Ripon, WI	01/20/2002
Goldstein, Marshall Upper St Clair, PA	01/20/2002
Lee, Wendy Louise Waite Greeley, CO	01/20/2002
Leone, Michael A Indianapolis, IN	01/20/2002
Teal, Robin Louise Cary, NC	01/20/2002
Patient Abuse/Neglect Convictions	
Benjamin, Kimberly Isanti, MN	01/20/2002
Coviello, Peter Raymond Whitney, TX	01/20/2002
Euerle, Nancy Newport, MN	01/20/2002
Finch, Brenda Ona San Antonio, TX	01/20/2002
Lewis, Shentelle Lanelle Jeanerette, LA	01/20/2002
Miguel, Alejandra C Lihue, HI	01/20/2002
Nelson, Konrad P Orem, UT	01/20/2002
Perdue, Elizabeth Lawton, OK	01/20/2002
Pilant, Jesse Wayne Tucson, AZ	01/20/2002
Rogers, Harold Clifton Elk City, OK	01/20/2002
Smith, Kevin Bernard Laurel, MS	01/20/2002
White, Tonya Y Tulsa, OK	01/20/2002
License Revocation/Suspension/ Surrendered	
Alvarez, Mark T Cranston, RI	01/20/2002
Barcelos, Susana M Chino, CA	01/20/2002
Bennett, Freeman Thomas Jackson, MS	01/20/2001
Blaylock, Tina Folies Indianapolis, IN	01/20/2002
Bradshaw, Benjamin F Jerome, ID	01/20/2002
Brosemer, Dwaine G Poway, CA	01/20/2002
Brown, Tracey Lee Tulsa, OK	01/20/2002
Bullington, Tom Wilson Jr Wichita Falls, TX	01/20/2002
Bullock, Johnny Ray Jr Columbia, MS	01/20/2002
Bustos, Rodolfo Calara	01/20/2002