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 FOSRENOL is 2,449 days. Of this time, 1,538 days occurred during the testing phase of the regulatory review period, while 911 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*: February 13, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 13, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 30, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for FOSRENOL (NDA 21–468) was initially submitted on April 30, 2002.

3. *The date the application was approved*: October 26, 2004. FDA has verified the applicant's claim that NDA 21–468 was approved on October 26, 2004.

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 951 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 July 23, 2007. 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 November 19, 2007. 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. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–9787 Filed 5–21–07; 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).

Dates and Times: June 13, 2007, 9 a.m.–5 p.m. June 14, 2007, 8:30 a.m.–3 p.m.

Place: Four Points by Sheraton Washington DC Downtown Hotel, 1201 K Street, NW.,Washington, DC 20005,(202)–289–7600.

Status: The meeting is open to the public with attendance limited to space availability.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of pregnant women and infants, and factors affecting the continuum of care with respect to maternal and child health care. It includes outcomes following childbirth; strategies to coordinate the variety of Federal, State, 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 Program and *Healthy People 2010* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Cesarean section and its effect on pre-term and infant mortality, SIDS and related causes of infant death and Preconceptional care. Proposed agenda items are subject to change as priorities indicate.

Time will be provided for public comments limited to five minutes each; comments are to be submitted no later than June 1, 2007.

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, ParklawnBuilding, 5600 Fishers Lane, Rockville, MD 20857, *Telephone:* (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, PhD, M.P.H., HRSA, Maternal and Child Health Bureau, *telephone:* (301) 443–6332, *e-mail: David.delaCruz@hrsa.hhs.gov.*

Dated: May 15, 2007.

Caroline Lewis,

Associate Administrator for Management.

[FR Doc. E7–9784 Filed 5–21–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605–56606 as amended November 6, 1995; and as last amended at 72 FR 19540–19544, April 18, 2007.)

This notice reflects organizational changes in the Health Resources and Services Administration, Bureau of Primary Health Care (RC). Specifically, this notice updates the mission statement of the Bureau of Primary Health Care (RC) and the functional statement of the Office of the Associate Administrator (RC), and deleted the Office of Administrative Management (RCM).

Chapter RC, Bureau of Primary Health Care

Section RC, 00 Mission

Delete in its entirety and replace with the following:

The mission of the Bureau of Primary Health Care is to improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services.

Section RC–10, Organization

Delete in its entirety and replace with the following:

The Bureau of Primary Health Care (BPHC) is headed by an Associate Administrator, who reports directly to

the Administrator, Health Resources and Services Administration. The Bureau of Primary Health Care includes the following components:

(1) Office of the Associate Administrator (RC);

(2) Office of Minority and Special Populations (RCG);

(3) Office of Policy and Program Development (RCH);

(4) Office of Quality and Data (RCK);

(5) Eastern Division (RCN);

(6) Central Mid-Atlantic Division (RCP);

(7) Western Division (RCQ);

(8) Division of National Hansen's Disease Programs (RC7); and

(9) Division Immigration Health Service (RC9).

Section RC–20, Functions

(1) Delete the functional statement for the Office of the Associate Administrator (RC) and replace in its entirety; and (2) Delete the functional statement for the Office of Administrative Management (RCM).

Office of the Associate Administrator (RC)

Provides overall leadership, direction, coordination, and planning in support of Bureau of Primary Health Care programs that are designed to improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. Specifically, (1) Establishes program goals, objectives and priorities, and provides oversight as to their execution; (2) plans, directs, coordinates and evaluates Bureau-wide management activities; (3) maintains effective relationships within HRSA and with other Department of Health and Human Services (HHS) organizations, other Federal agencies, State and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the Nation's underserved and vulnerable populations; and (4) plans, directs, and coordinates Bureau-wide administrative management activities, *i.e.*, budget, finance, personnel, procurements, delegations of authority, emergency planning, training, executive secretariat, and has responsibilities related to the awarding of BPHC grant and contract funds.

Section RC–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon the date of signature.

Dated: May 15, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–9786 Filed 5–21–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Compositions and Methods for Increasing Recombinant Protein Yields Through the Modification of Cellular Properties

Description of Technology: This technology relates to compositions and methods for improving the growth characteristics of cells engineered to produce biologically active products such as antibodies or glycosylated proteins. Featured is a method that uses gene candidates (e.g., cdkl3, siat7e, or lama4), or their expressed or inhibited products in cell lines, such as Human Embryonic Kidney (including HEK–293), HeLa, or Chinese Hamster Ovary (CHO). The gene expression modulates growth characteristics, such as adhesion properties, of the cell lines thereby increasing recombinant protein yields and reducing product production costs.

Applications: This technology may be used to improve production of therapeutic and/or diagnostic compounds, including therapeutic proteins or monoclonal antibodies from mammalian cells. Optimization of mammalian cells for use as expression systems in the production of biologically active products is very difficult. For certain applications, anchorage-independent cell lines may be preferred, whereas for other applications, a cell line that adheres to a surface, e.g. is anchorage-dependent, may be preferable. This technology provides a method for identifying a gene whose expression modulates such cellular adhesion characteristics. This method thus leads to an increase in the expression or yield of polypeptides, including therapeutic biologicals, such as antibodies, cytokines, growth factors, enzymes, immunomodulators, thrombolytics, glycosylated proteins, secreted proteins, and DNA sequences encoding such polypeptides and a reduction in the associated costs of such biological products.

Advantages: This technology offers the ability to improve yields and reduce the cost associated with the production of recombinant protein products through the selection of cell lines having: Altered growth characteristics; altered adhesion characteristics; altered rate of proliferation; improvement in cell density growth; improvement in recombinant protein expression level.

Market: Biopharmaceuticals, including recombinant therapeutic proteins and monoclonal antibody-based products used for in vivo medical purposes and nucleic acid based medicinal products now represent approximately one in every four new pharmaceuticals on the market. The market size has been estimated at $33 billion in 2004 and is projected to reach $70 billion by the end of the decade. The list of approved biopharmaceuticals includes recombinant hormones and growth factors, mAB-based products and therapeutic enzymes as well as recombinant vaccines and nucleic acid based products.

Mammalian cells are widely used expression systems for the production of biopharmaceuticals. Human embryo kidney (including HEK–293) and Chinese hamster ovary (CHO) are host cell of choice. The genes identified in this technology (e.g., cdkl3, sia7e, or lama4) can be used to modify these important cell based systems.

This technology is ready for use in drug/vaccine discovery, production and development. The technology provides