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