ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 1-day public workshop, cosponsored with the American Thyroid Association (ATA), entitled ''Propylthiouracyl (PTU)-Related Liver Toxicity.'' This public workshop is intended to provide a public forum for discussion of the clinical, scientific, and regulatory issues pertaining to PTU-induced hepatitis to seek constructive input from academia, regulatory scientists, and other interested parties on the topic of PTU-induced hepatitis. The input from this public workshop will help the ATA to develop guidelines for the management of hyperthyroidism and help inform FDA about necessary changes to prescription drug labeling for PTU.

DATES: This public workshop will be held on Saturday, April 18, 2009, from 8 a.m. to 3:30 p.m. However, depending on the level of public participation, the meeting may be extended or may end early. Written or electronic comments will be accepted after the workshop until June 19, 2009.

ADDRESSES: The public workshop will be held at the Madison Hotel at 1177 15th St., NW., Washington, DC 20005, 202–862–1600. We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket by June 19, 2009.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: *http://www.regulations.gov*.

Comments should be identified with the docket number found in brackets in the heading of this document.

Transcripts of the workshop will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 45 days after the workshop.

FOR FURTHER INFORMATION CONTACT: Jeff O'Neill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6167, Silver Spring, MD 20903, 301–796–0777, FAX: 301–847–8753, e-mail: *jeff.o'neill@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

PTU-related liver toxicity has been reported in the published literature, and while direct comparative studies to another approved anti-thyroid medication, methimazole, are lacking, case series and postmarketing adverse event reports suggest a greater risk associated with PTU than methimazole. From prescription usage data, it appears that PTU is used less frequently than methimazole with perhaps a preferential use during pregnancy because of concerns about a rare congenital defect described in case reports of methimazole use. However, some data question whether an advantage of PTU use over methimazole exists, even during pregnancy.

FDA and ATA are sponsoring this open public discussion involving academia, regulatory scientists, and other interested parties on the topic of PTU-induced hepatitis, because it is important to the health of patients with thyroid disease that the applicable scientific, clinical, and regulatory issues are raised and fully elucidated, and, to the greatest extent possible, consensus is reached.

The ATA serves clinicians, scientists, and patients to facilitate open interchange and dissemination of scientific knowledge. The workshop is intended to provide a forum for discussion of the clinical, scientific, and regulatory issues pertaining to PTU-induced hepatitis.

II. Registration

There is no fee to attend the workshop, and attendees do not need to register. Seating will be on a first-come, first-served basis. If you need special accommodations because of disability, please contact Jeff O'Neill (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

Dated: April 2, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–7993 Filed 4–7–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Meeting; Advisory Council on Blood Stem Cell Transplantation

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

ACTION: Notice of Meeting of the Advisory Council on Blood Stem Cell Transplantation.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the fourth meeting of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT), Department of Health and Human Services (HHS). The meeting will be held from approximately 8:30 a.m. to 5 p.m. on May 12, 2009, at the Bethesda North Marriott Hotel and Convention Center, 5701 Marinelli Road, Bethesda, MD 20852. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended), the ACBSCT was established to advise the Secretary of HHS and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI) Program. ACBSCT is composed of up to 25 members, including the Chair, serving as Special Government Employees. The current membership includes representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of a bone marrow transplant; recipients of a cord blood transplant; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists; hematology and transfusion medicine researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public.

The Council will hear reports from three ACBSCT Work Groups: Cord Blood Accreditation Organization and Recognition Process, Scientific Factors Necessary to Define a Cord Blood Unit as High Quality, and Informed Consent. The Council also will hear presentations and discussions on the following topics: recent clinical developments and current issues, adult donor recruitment: Strategies and challenges, and future council activities.

The draft meeting agenda and a registration form will be available on or about April 13, 2009, on HRSA's Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/*

AdvisoryCouncil/index.html. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701 ATTN: Rebecca Pascoe. Registration can also be completed electronically at *https://www.team-psa.com/dot/spring2009/acbsct/.* Individuals without access to the Internet who wish to register may call Rebecca Pascoe with PSA at (703) 234–1747.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACBSCT Executive Secretary, Remy Aronoff, in advance of the meeting. Mr. Aronoff may be reached by telephone at 301–443–3264, e-mail: *Remy.Aronoff@hrsa.hhs.gov* or in writing at the address provided below. Management and support services for ACBSCT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations and Council discussions, members of the public will have an opportunity to provide comments. Because of the Council's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACBSCT meeting. Meeting summary notes will be made available on HRSA's Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html.*

Dated: April 1, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–7964 Filed 4–7–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Office of Rural Health Policy; Notice of Meetings

Name: Office of Rural Health Policy, Health Resources and Services Administration (HRSA), HHS.

Dates and Times: April 24, 2009, 8 a.m.—3 p.m. in Albuquerque, NM. May 18, 2009, 8 a.m.—3 p.m. in Seattle, WA. June 26, 2009, 8 a.m.—3 p.m. in Omaha, NE.

Place: The Albuquerque Marriott, 2101 Louisiana Boulevard, NE., Albuquerque, NM 87110, Phone: 505–881–6800.

The Seattle Airport Marriott, 3201 South 176th Street, Seattle, WA 98188, Phone: 206–241–2000.

The Omaha Marriott, 10220 Regency Circle, Omaha, NE 68114, Phone: 402–399–9000.

Status: The meetings will be open to the public.

Purpose: The Office of Rural Health Policy (ORHP) will hold a series of meetings to gather information on potential definitions of the terms Frontier or Remote Areas.

Currently the most widely used definition within the Department of Health and Human Services (DHHS) requires that the population density of a county consist of six or fewer persons per square mile. The use of whole counties as the unit of measurement can lead to inclusion of large population centers in large area counties that still have a low overall population density.

Use of population density alone as a measure of remoteness is also inappropriate for islands as the population density can far exceed 6 persons per square mile even though the island is isolated and lacks access to services and resources.

ORHP has used the Rural-Urban commuting area (RUCA) codes to identify rural areas located in Metropolitan counties. Metropolitan counties are defined by the Office of Management and Budget of the White House but can contain substantial rural areas due to geographic barriers, distance or other factors. RUCAs are based on a sub-county unit, the Census Tract, and take into account population density, urbanization, and daily commuting patterns. Every Census tract is assigned a code based on these factors. While ORHP has chosen to define Metropolitan tracts with RUCA codes from 4 through 10 as ''rural'' for purposes of grant eligibility, the codes have not been used to identify ''Frontier'' or remote areas.

In order to pursue a more accurate definition of Frontier/Remote areas, ORHP has entered into agreements with L. Gary Hart and the Economic Research Service (ERS) of the US Department of Agriculture (USDA). Dr. Hart and ERS also developed the RUCAs with support from ORHP. As work on this definition proceeds ORHP will hold a series of meetings to gather information from interested parties and the public.

While a robust, quantitative definition of Frontier/Remote areas may have future programmatic uses, the immediate goal of ORHP and ERS is to make this work available for research purposes.

For Further Information Contact: Direct requests for additional information to Mr. Steven Hirsch, Health Resources and Services Administration, Office of Rural Health Policy, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–7322. E-mail: *shirsch@hrsa.gov.*

Dated: April 3, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–8013 Filed 4–7–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Part C Early Intervention Services Grant Under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HHS).

ACTION: Notice of noncompetitive transfer of Part C funds from Cathedral Healthcare System to Saint Michael's Medical Center.

SUMMARY: HRSA will be transferring Part C funds to Saint Michael's Medical Center as a noncompetitive replacement award in order to ensure continuity of critical HIV medical care and treatment services and to avoid a disruption of HIV clinical care to clients in Metropolitan Newark, and Essex County in New Jersey.

SUPPLEMENTARY INFORMATION: *Grantee of record:* Cathedral Healthcare System.

Intended recipient of the award: Saint Michael's Medical Center, Newark, New Jersey.

Amount of the award: $537,607 to ensure ongoing clinical services to the target population.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff–51.

CFDA Number: 93.918.

Project period: April 1, 2005 to March 31, 2010. The period of support for the replacement award is from April 1, 2009 to March 31, 2010.

Justification for the Exception to Competition: Critical funding for HIV medical care and treatment services to clients in Metropolitan Newark and Essex County in New Jersey will be continued through a noncompetitive supplement to Saint Michael's Medical Center, a prior sub-contractor of Cathedral Healthcare System, the grantee of record in Newark, New Jersey. This is a temporary replacement award as the previous grant recipient serving this population notified HRSA that they will not continue providing services after March 31, 2009. The Cathedral Healthcare System, the former grantee, has ceased governance and operations of its three hospitals. Saint Michael's Medical Center is the best qualified recipient for this supplement, as it already serves most of the former grantee's patients ensuring continuity of care, and can continue to provide critical services with the least amount of disruption to the service population while the service area is re-competed.

This supplement will cover the time period from April 1, 2009, through