ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments on the guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002, 301–796–1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of August 5, 2008 (73 FR 45467), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter.'' The notice gave interested persons an opportunity to submit comments by October 6, 2008.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 4C: Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter'' was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2008.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance. When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/guidelines.htm*.

Dated: March 31, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–7905 Filed 4–7–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration.

[Docket No. FDA–2009–N–0167]

Propylthiouracyl (PTU)-Related Liver Toxicity; Public Workshop

AGENCY: Food and Drug Administration, HHS.

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/*