2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: December 15, 2004. The applicant claims December 14, 2004, as the date the new drug application (NDA) for Uloric (NDA 21–856) was initially submitted. However, FDA records indicate that NDA 21–856 was submitted on December 15, 2004.

3. The date the application was approved: February 13, 2009. FDA has verified the applicant’s claim that NDA 21–856 was approved on February 13, 2009.

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 5 years 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) either electronic or written comments and ask for a redetermination by November 9, 2010. 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 March 9, 2011. 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.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Jane A. Axelrad,
Associate Director for Policy, Center for Drug Evaluation and Research.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
Board of Scientific Counselors, National Center for Health Statistics, (BSC, NCHS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the following meeting of the aforementioned committee.

Times and Dates:
11 a.m.–5:30 p.m., September 23, 2010.
8:30 a.m.–2 p.m., September 24, 2010.
Place: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.
Status: This meeting is open to the public on a first come, first serve basis up to the meeting room’s capacity. However, visitors must be processed in accordance with established Federal policies and procedures. For foreign nationals or non-US citizens, pre-approval is required (please contact Athelia Harris, 301–458–4261, adw1@cdc.gov or Virginia Cain, vcin@cdc.gov at least 10 days in advance for requirements). All visitors are required to present a valid form of picture identification issued by a state, Federal or international government. As required by the Federal Property Management Regulations, Title 41, Code of Federal Regulation, Subpart 101–20.301, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters to be discussed: The agenda will include welcome remarks by the Director, NCHS; update on the long-term care research program; a discussion of the NCHS visitation program and an open session for comments from the public.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by September 17, 2010.

The agenda items are subject to change as priorities dictate.

Contact person for more information: Virginia S. Cain, PhD, Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7211, Hyattsville, Maryland 20782, telephone (301) 458–4500, fax (301) 458–4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Nominations for AHRQ Study Section Members

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for nominations for public members.

SUMMARY: In accordance with Title IX of the Public Health Service Act, see 42 U.S.C. 299c–1, and AHRQ’s grant and contract regulations, 42 CFR part 67, applications submitted to AHRQ will be evaluated using the AHRQ peer review process to ensure a fair, equitable, and unbiased evaluation of their scientific and technical merit. The initial peer review of grant applications involves an assessment conducted by panels of experts established to include pertinent scientific disciplines and medical specialty areas. The confidential part of the peer review meetings devoted to critical evaluations will be closed meetings in accordance with section 10(d) of the Federal Advisory