FDA has determined that the applicable regulatory review period for SAPHRIS is 4,547 days. Of this time, 3,833 days occurred during the testing phase of the regulatory review period, while 714 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*: March 4, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 4, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: August 31, 2007. FDA has verified the applicant's claim that the new drug application (NDA) for SAPHRIS (NDA 22–117) was submitted on August 31, 2007.

3. *The date the application was approved*: August 13, 2009. FDA has verified the applicant's claim that NDA 22–117 was approved on August 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 1,827 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**) 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.

Dated: August 13, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–22519 Filed 9–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0527]

Determination of Regulatory Review Period for Purposes of Patent Extension; ULORIC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ULORIC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

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

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ULORIC (febuxostat). ULORIC is indicated for chronic management of hyperuricemia in patients with gout. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ULORIC (U.S. Patent No. 5,614,520) from Teijin Pharma Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 17, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ULORIC represented the first permitted commercial marketing or use of the product. Thereafter, 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 ULORIC is 3,395 days. Of this time, 1,873 days occurred during the testing phase of the regulatory review period, while 1,522 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*: October 31, 1999. The applicant claims April 28, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 31, 1999, which was 30 days after FDA receipt of the active IND.

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.

Dated: August 13, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–22521 Filed 9–9–10; 8:45 am]

BILLING CODE 4160–01–S

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 Althelia Harris, 301–458–4261, *adw1@cdc.gov* or Virginia Cain, *vcain@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.

Dated: September 3, 2010.

Elaine L. Baker,

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

[FR Doc. 2010–22594 Filed 9–9–10; 8:45 am]

BILLING CODE 4163–18–P

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