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

Committee Act, as amended (5 U.S.C. Appendix 2).

AHRQ is seeking nominations to fill approximately 20 to 30 percent of its study section membership, across the following study sections:

(1) Health System Research (HSR),

(2) Health Care Technology and Decision Sciences (HCTDS),

(3) Health Care Quality and Effectiveness Research (HCQER), and

(4) Health Care Research Training (HCRT).

The primary research foci and functions of these four study sections are described on the AHRQ Web site: (*http:Ilwww.AHRQ .qovlfundlpeerrevlpeerdesc. htm*).

Individuals from the health services research and health care community who could serve as peer reviewers on these study sections are sought to replace study section members whose terms have expired. In sending your nomination, please specify the nominee's professional/scientific/technical expertise, affiliations and full contact information, if this information is available.

Factors that will be considered in the selection of individuals to serve on study sections include: competence in a scientific, technical or clinical discipline or research specialty, particularly in health services research; fairness and evenhandedness in judgment and review; ability to work effectively in a group context; and commitment to complete work assignments.

A diversity of perspectives is valuable to AHRQ's work. To help obtain a diversity of perspectives among nominees, AHRQ encourages nominations of women and members of minority populations. AHRQ also seeks broad geographic representation.

DATES: AHRQ would like to receive your recommendations no later than Friday, October 1,2010.

ADDRESSES: Please direct your correspondence to: Kishena C. Wadhwani, PhD., M.P.H., Director, Division of Scientific Review (DSR), Office of Extramural Research, Education and Priority Populations (OEREP), Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (DHHS), 540 Gaither Road, Room 2032, Rockville, MD 20850, Phone: (301) 427–1556, Fax: (301) 427–1562, e-mail: *Kishena.WadhwanjAHRQ hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Kishena C. Wadhwani, PhD., M.P.H. (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

Background

Currently, AHRQ has one chartered Health Services Research Initial Review Group (IRG) responsible for the peer review of research and training grant applications submiffed for funding consideration. The IRG is to advise the Director of the Agency on matters related to scientific and technical merit of research grant proposals to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.

This IRG is currently comprised of four subcommittees or study sections, each with a particular research focus around which peer reviewers' expertise is assembled. These study sections convene three times per year to review the grant applications submitted to the three different submission cycles. Study section members are appointed for up to a maximum of four years.

Dated: September 1, 2010.

Carolyn M. Clancy,

Director, AHRQ.

[FR Doc. 2010–22544 Filed 9–9–10; 8:45 am]

BILLING CODE 416Q–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0444]

Schmid Laboratories, Inc. et al.; Withdrawal of Approval of Five New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five new drug applications (NDAs) from multiple holders of these applications. The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for the applications.

DATES: Effective September 10, 2010.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of September 24, 2009 (74 FR 49760), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of five NDAs because the firms had failed to submit the required annual reports for these applications. The holders of these applications did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the five applications listed in table 1 of this document.

TABLE 1.

Application No.	Drug	Applicant
NDA 5–766	Ramses Vaginal Jelly	Schmid Laboratories, Inc., Route 46 West, Little Falls, NJ 07424
NDA 7–220	Synthetic Vitamin A (vitamin A palmitate)	Merck & Co., Inc., 770 Sumneytown Pike, P.O. Box 4, West Point, PA 19486
NDA 8–595	Immolin Vaginal Cream Jel	Schmid Laboratories, Inc.
NDA 8–612	Silicote (simethicone) Ointment	Arnar-Stone Laboratories, Inc., 601 East Kensington Rd., Mount Prospect, IL 60056