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

TABLE 1.—Continued

Application No.	Drug	Applicant
NDA 10–915	Q.E.D. Hairgroom (captan)	A.R. Winarick, Inc., 783 Palisade Ave., Cliffside, NJ 07010

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated by the Commissioner, finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, we find that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 10, 2010.

Dated: August 31, 2010.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2010–22603 Filed 9–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2010–0075]

Privacy Act of 1974; Privacy Act of 1974: Department of Homeland Security/ALL–031 Information Sharing Environment Suspicious Activity Reporting Initiative System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to establish a new Department of Homeland Security system of records titled, "Department of Homeland Security/ALL—031 Information Sharing Environment Suspicious Activity Reporting Initiative System of Records." This system of records will allow DHS to compile suspicious activity report data that meet the Information Sharing Environment Suspicious Activity Reporting Functional Standard and share these Suspicious Activity Reporting data with authorized participants in the Nationwide Suspicious Activity Reporting Initiative, including other DHS components, Federal departments and agencies, State, local and Tribal law enforcement agencies, and the private sector. Additionally, the Department of Homeland Security is issuing a Notice of Proposed Rulemaking to exempt this system from certain provisions of the Privacy Act elsewhere in the **Federal Register**. This newly established system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before October 12, 2010. This new system will be effective October 12, 2010.

ADDRESSES: You may submit comments, identified by docket number DHS–2010–0075 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 703–483–2999.
- *Mail:* Mary Ellen Callahan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Ronald Athmann (202–447–4332), Office of Intelligence and Analysis, Department of Homeland Security, Washington, DC 20528. For privacy issues please contact: Mary Ellen Callahan (703–235–0780), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) proposes to establish a new DHS system of records titled, "DHS/ALL–031 Information Sharing Environment (ISE) Suspicious Activity Reporting (SAR) Initiative System of Records."

This system of records will allow DHS components that produce, receive, and store suspicious activity reports (SARs) pursuant to their existing authorities, responsibilities, platforms, and programs to compile and share report data that also meet the ISE–SAR Functional Standard with authorized participants in the Nationwide SAR Initiative (NSI) including, Federal departments and agencies, State, local and Tribal law enforcement agencies, and the private sector. The NSI is one of a number of government-wide efforts designed to implement guidelines first issued by the President on December 16, 2005, for establishing the ISE pursuant to section 1016 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), as amended. The NSI establishes a nationwide capability to gather, document, process, analyze and share information about suspicious activity, incidents, or behavior reasonably indicative of terrorist activities (hereafter collectively referred to as suspicious activity or activities) to enable rapid identification and mitigation of potential terrorist threats.

There is a long history of documenting of suspicious activity, particularly in the law enforcement community; these reports are sometimes referred to as suspicious activity reports, tips and leads, or other similar terms. Federal, State, local and Tribal agencies and the private sector currently collect and document suspicious activities in support of their responsibilities to investigate and prevent potential crimes, protect citizens, and apprehend and prosecute criminals. Since some of these documented activities may bear a nexus to terrorism, the Program Manager for the Information Sharing Environment (PM–ISE) has developed a standardized process for identifying, documenting, and sharing terrorism-related SAR data (hereinafter referred to as an "ISE–SAR"), which meet the definition and criteria set forth in the ISE Functional Standard Suspicious Activity Reporting, (Version 1.5, May 2009) to the maximum extent possible consistent with the protection of individual privacy, civil rights, and civil liberties. The Functional Standard defines an ISE–SAR as official documentation of observed behavior determined to have a potential nexus to terrorism (*i.e.,* to be reasonably