appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 12 and 13, 2009, the Committee will discuss strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. For more specific agenda topics, please visit the following Web site and scroll down to the appropriate advisory committee link (*http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*), or call the FDA Advisory Committee Information Line as detailed under ''*Contact Person*''. FDA intends to provide specific agenda topics at both these locations no later than 15 days before the meeting.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 4, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 12, 2009, and between approximately 10:30 a.m. and 11:30 a.m. on November 13, 2009. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 4, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 5, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lee Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 18, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23001 Filed 9–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel. ''NIAID Science Education Awards.''

Date: October 5, 2009.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Jay Bruce Sundstrom, PhD, Scientific Review Official, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 2217, 6700B Rockledge Drvie, MSC–7616, Bethesda, MD 20892–7616, (301) 496–2550, *sundstromj@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 18, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23121 Filed 9–23–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0444]

Schmid Laboratories, Inc. et al.; Proposal To Withdraw Approval of Five New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity to request a hearing on the agency's proposal to withdraw approval of five new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Submit written requests for a hearing by October 26, 2009; submit data and information in support of the hearing request by November 23, 2009.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. FDA–2009–N–0444 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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). The holders of the approved applications listed in table 1 of this document have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.

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
NDA 10–915	Q.E.D. Hairgroom (captan)	A.R. Winarick, Inc., 783 Palisade Ave., Cliffside, NJ 07010

Therefore, notice is given to the holders of the approved applications listed in table 1 of this document and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file the following: (1) A written notice of participation and request for a hearing (see **DATES**), and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, or on the Internet at *http://www.regulations.gov*.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs.

Dated: September 9, 2009.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E9–23005 Filed 9–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0383]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative on the Tobacco Products Scientific Advisory Committee and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative on the Tobacco Products Scientific Advisory Committee and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee. This meeting was announced in the **Federal Register** of August 26, 2009 (74 FR 43140). The amendment is being made to reflect changes in the **DATES**, **ADDRESSES**, and **Selection Procedure** portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Food and Drug Administration, Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850–3229, 301–796–3369, FAX: 301–595–7946, e-mail: *Teresa.Hays@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 26, 2009, FDA announced a Request for Notification From Industry Organizations Interested in Participating