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are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.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

in the Selection Process for a Nonvoting Industry Representative on the Tobacco Products Scientific Advisory Committee and Request for Nominations for a Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee of the Tobacco Products Scientific Advisory Committee.

On page 43140, in the third column, the **DATES** portion of the document is changed to read as follows:

**DATES**: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by October 26, 2009, for vacancies listed in the notice. Concurrently, nomination material for prospective candidates should be sent to the FDA by October 26, 2009.

On page 43140, in the first column, the **ADDRESSES** portion of the document is changed to read as follows:

**ADDRESSES**: All nominations for membership should be sent to Teresa L. Hays, Food and Drug Administration, Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850–3229, 301–796–3699, FAX: 301–595–7946, e-mail: *Teresa.Hays@fda.hhs.gov*.

On page 43141, beginning in the first column, the text in the **II. Selection Procedure** portion of the document is changed to read as follows:

**Selection Procedure**

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **ADDRESSES**) within 30 days of publication of this document. Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the Tobacco Products Scientific Advisory Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 18, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9–23009 Filed 9–23–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOMELAND SECURITY

### National Protection and Programs Directorate; Infrastructure Protection Data Call Survey

**AGENCY:** National Protection and Programs Directorate, DHS.

**ACTION:** 60-Day Notice and request for comments; New Information Collection Request: 1670—NEW.

**SUMMARY:** The Department of Homeland Security, National Protection and Programs Directorate, has submitted the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

**DATES:** Comments are encouraged and will be accepted until November 23, 2009. This process is conducted in accordance with 5 CFR 1320.1.

**ADDRESSES:** Written comments and questions about this Information Collection Request should be forwarded to NPPD/IP/IICD, Attn.: Mary Matheny-Rushdan, *mary.matheny-rushdan@dhs.gov.*

**SUPPLEMENTARY INFORMATION:** The U.S. Department of Homeland Security (DHS) is the lead coordinator in the national effort to identify and prioritize the country's critical infrastructure and key resources (CIKR). At DHS, this responsibility is managed by the Office of Infrastructure Protection (IP) in the National Protection and Programs Directorate (NPPD). In FY2006, IP engaged in the annual development of a list of CIKR assets and systems to improve IP's CIKR prioritization efforts; this list is called the Critical Infrastructure List. The Critical Infrastructure List includes assets and systems that, if destroyed, damaged or otherwise compromised, could result in significant consequences on a regional or national scale.

The IP Data Call is administered out of the Infrastructure Information Collection Division (IICD) in the Office of Infrastructure Protection (IP). The IP Data Call provides opportunities for States and territories to collaborate with DHS and its Federal partners in CIKR protection. DHS, State and territorial Homeland Security Advisors (HSA), Sector Specific Agencies (SSA), and territories build their CIKR data using the IP Data Call application. To ensure that HSAs, SSAs and territories are able to achieve this mission, IP requests opinions and information in a survey from IP Data Call participants regarding the IP Data Call process and the Web-based application used to collect the CIKR data. The survey data collected is for internal IICD and IP use only.

IICD and IP will use the results of the IP Data Call Survey to determine levels of customer satisfaction with the IP Data Call process and the IP Data Call application and prioritize future improvements. The results will also allow IP to appropriate funds cost-effectively based on user need, and improve the process and application.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

**Analysis**

*Agency:* Department of Homeland Security, National Protection and Programs Directorate.

*Title:* IP Data Call Survey.

*Form:* Not Applicable.

*OMB Number:* 1670—NEW.

*Affected Public:* State, Local, or Tribal Government.

*Number of Respondents:* 138.

*Estimated Time per Respondent:* 2 hours.

*Total Burden Hours:* 276.