DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0246]

Menley & James Laboratories, Inc. et al.; Proposal to Withdraw Approval of Six 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 six 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 July 30, 2007; submit data and information in support of the hearing request by August 27, 2007.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 2007N–0246 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 (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 the following table 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.

Application No.	Drug	Applicant
NDA 6–410	Benzedrex (propylhexadrine) Nasal Spray	Menley & James Laboratories, Inc., Commonwealth Corporate Center, 100 Tournament Drive, Horsham, PA 19044
NDA 7–518	Synthetic Vitamin A	Pfizer Laboratories, Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017
NDA 8–837	Isoniazid Tablets	Barnes Hind, 895 Kifer Rd., Sunnyvale, CA 94806
NDA 8–851	NDK Fluoride Dentrifice (sodium monofluorophosphate)	NDK Co., c/o J.W. Emmer/Kenneth Emmer, 215 Genevieve Dr., Lafayette, LA 70503
NDA 9–395	Paskalium (potassium aminosalicylate)	Glenwood, 111 Cedar Lane, Englewood, NJ 07631
NDA 19–518	Extra Strength Aim (sodium monofluorophosphate)	Chesebrough-Ponds USA Co., 33 Benedict Pl., P.O. Box 6000, Greenwich, CT 06836–6000

Therefore, notice is given to the holders of the approved applications listed in the table 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 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 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 NDA 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 (the Commissioner) 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 section 301 of the act (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.

This notice is issued under section 505 of the act and under authority delegated to the Director, Center for

Drug Evaluation and Research, by the Commissioner.

Dated: June 11, 2007.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E7–12494 Filed 6–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Dermatologic and Ophthalmic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 1, 2007, from 8 a.m. to 12:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD.

Contact Person: Sohail Mosaddegh, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, fax: 301–827–6776, e-mail: *Sohail.Mosaddegh@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512534 or 3014512535. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committees will meet in joint session to be briefed on iPLEDGE, the risk management program for isotretinoin products. Presentations will provide updates on risk management activities for isotretinoin since the full implementation of iPLEDGE on March 1, 2006.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and 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 July 11, 2007. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 11:15 a.m. 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 July 2, 2007. 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 July 3, 2007.

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 John Lauttman, 301-827-7001, at least 7 days in advance of the meeting.

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

Dated: June 21, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–12501 Filed 6–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; National Physician Survey of Practices on Diet, Physical Activity, and Weight Control

SUMMARY: In compliance with the provisions of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Physician Survey of Practices on Diet, Physical Activity, and Weight Control. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will obtain current, national data on primary care physicians' knowledge, attitudes, and practices related to diet, physical activity, and weight control. Obesity, poor diet, and lack of physical activity are becoming recognized as major public health problems in the United States, and have been linked to increased risk, adverse prognosis, and poor quality of life for cancer and many other chronic diseases. The data collected in this study will support and further NCI work in monitoring and evaluating providers' cancer prevention knowledge, attitudes, and practices and their impact on population health, as well as enable monitoring of progress toward major cancer control goals. Data from the survey will be used to profile existing physician practice, understand barriers to counseling and referral, and to inform methods for improving the utilization of these services for adults and children. Two questionnaires, one sent to physicians and one sent to their practice administrators, will be administered by mail or telephone to a randomly-selected national sample of 2,000 physicians belonging to primary care specialties. Study participants will be 2,000 practicing physicians who are family practitioners, general internists, pediatricians, and obstetrician/gynecologists and 2,000 practice administrators.