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Certifier J. Hawkins

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 [insert date 30 days after date of publication in the FEDERAL REGISTER]; submit data and information in support of the hearing request by [insert date 60 days after date of publication in the FEDERAL REGISTER].

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,

cd0730

2007N-0246

NPH 1

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 Dentrifce (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

Application No.	Drug	Applicant
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.

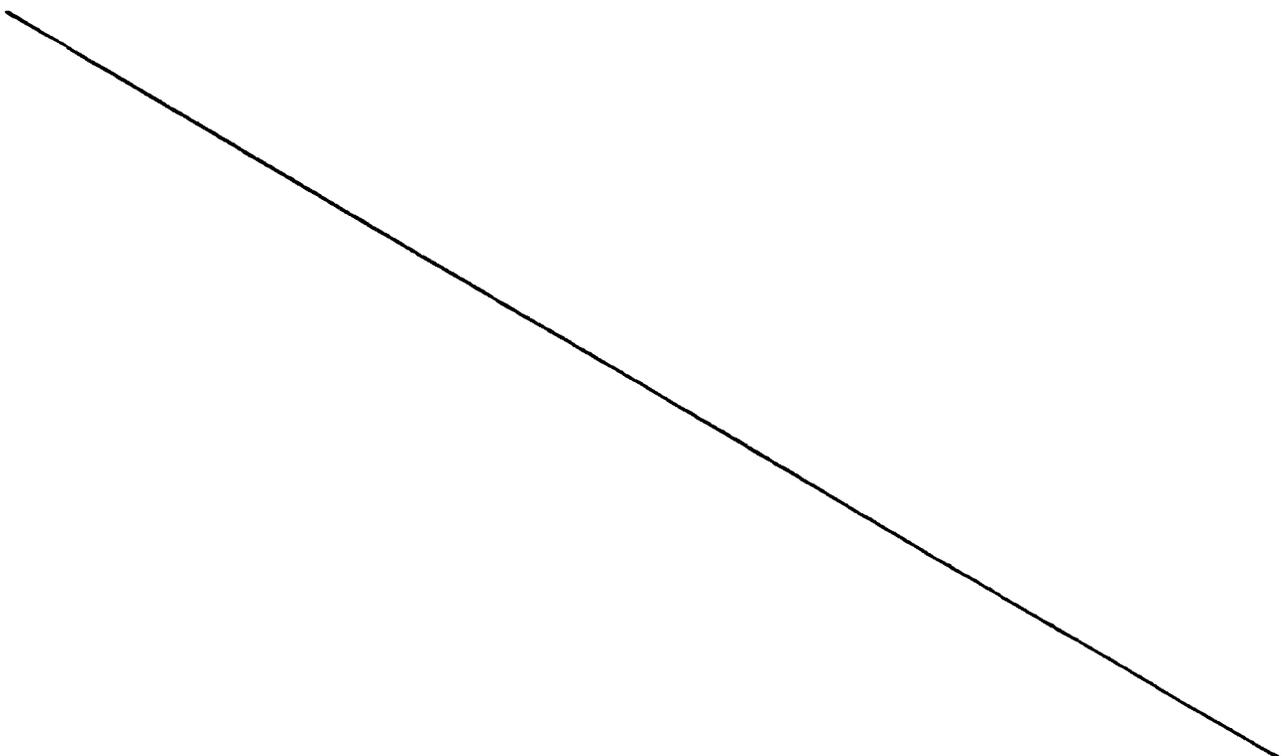
An applicant who decides to seek a hearing shall file the following: (1) A written notice of participation and request for a hearing (see DATES), and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see DATES). 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} ~~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.~~

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6-21-07

Dated: 6.11.07

June 11, 2007.

Douglas C. Throckmorton

Douglas C. Throckmorton,
Deputy Director,
Center for Drug Evaluation and Research.

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Dawn P. Hawkins