4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1285]

Smith Miller and Patch Inc. et al.; Proposal to Withdraw Approval of 14 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 14 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: Identify your requests for a hearing, supporting data, and other comments with Docket No. FDA-2013-N-1285, and submit this information 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 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.--Approved NDAs for Which Required Reports Have Not Been Made

Application No.	Drug	Applicant
NDA 004979	Multi-Vitamin Tablets	Smith Miller and Patch Inc., P.O. Box 367, San German, PR 00753
NDA 008176	Methostan (methandriol) Tablets	Do.
NDA 008326	Methischol (inositol/vitamin B12/racemethionine/choline chloride) Injection	USV Pharmaceutical Corp., 500 Virginia Dr., Fort Washington, PA 19034-2779
NDA 008362	Corticotropin Injection	Vitarine Pharmaceuticals Inc., 227-15 North Conduit Ave., Springfield Gardens, NY 11413
NDA 009346	ACTH (corticotropin) Injection	Parke-Davis, 201 Tabor Rd., Morris Plains, NJ 07950
NDA 009515	Hyrye (riboflavin 5'-phosphate sodium) Injection	S.F. Durst and Co., Inc., 5317-21 North Third St., Philadelphia, PA 19120
NDA 010415	Flamotide (riboflavin 5'-phosphate sodium) Injection	Philadelphia Ampoule Laboratories, 400 Green St., Philadelphia, PA 19123
NDA 010565	Duracton (corticotropin) Injection	Nordic Biochemicals Inc., 45 Bay State Rd., Boston, MA 02215
NDA 010791	Rubivite (cyanocobalamin) Injection	Bel Mar Laboratories, Inc., 6-10 Nassau Ave., Inwood, NY 11696
NDA 010831	Corticotropin Injection	Organics/LaGrange, Inc., 1935 Techny Rd., Suite 14, Northbrook, IL 60062
NDA 011015	RU-B-12-1000 (cyanocobalamin) Injection	Dow Pharmaceutical Corp., 9550 North Zionsville Rd., Indianapolis, IN 46268
NDA 011578	Efacin (niacin) Tablet	Person and Covey, Inc., 616 Allen Ave., Glendale, CA 91201
NDA 017861	Acthar Gel Synthetic (seractide acetate) Injection	Armour Pharmaceutical Co., P.O. Box 511, Kankakee, IL 60901
NDA 018087	Thyrel TRH (protirelin) Injection	Ferring Pharmaceuticals, Inc., 400 Rella Blvd., Suite 300, Suffern, NY 10901

Therefore, notice is given to the holders of the approved applications listed in table 1 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 (FD&C 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 FD&C 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 must 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, and will be posted to the docket at http://www.regulations.gov.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 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: October 30, 2013.

Janet Woodcock,
Director, Center for Drug Evaluation and Research.

[FR Doc. 2013-26491 Filed 11/05/2013 at 8:45 am; Publication Date: 11/06/2013]