4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

# Smith Miller and Patch, Inc. et al.; Withdrawal of Approval of 14 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 14 new drug applications (NDAs) from multiple holders of these applications. The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for the applications.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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).

In the Federal Register of November 6, 2013 (78 FR 66748), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 14 NDAs because the firms had failed to submit the required annual reports for these applications. The holders of these applications did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an

election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the 14 applications listed in table 1 of this document.

Table 1.--Approved NDAs for Which Required Reports Have Not Been Submitted

| 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 |

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated by the Commissioner, finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, we find that the

holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: November 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-27039 Filed 11/14/2014 at 8:45 am; Publication Date: 11/17/2014]