IV. Electronic Access

Persons with access to the Internet may obtain the document at: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm*, or *http://www.regulations.gov.*

Dated: November 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–27022 Filed 11–14–14; 8:45 am]

BILLING CODE 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: November 17, 2014.

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 November 17, 2014.

Dated: November 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–27039 Filed 11–14–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV)

Date And Time: December 4, 2014, 10:00 a.m. to 4:00 p.m. EDT

Place: Audio Conference Call and Adobe Connect Pro

The ACCV will meet on Thursday, December 4, 2014, from 10:00 a.m. to 4:00 p.m. (EDT). The public can join the meeting by:

1. (Audio Portion) Calling the conference Phone Number 877–917–4913 and providing the following information:

Leader's Name: Dr. A. Melissa Houston
Password: ACCV

2. (Visual Portion) Connecting to the ACCV Adobe Connect Pro Meeting using the following URL: *https://hrsa.connectsolutions.com/accv/* (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview.* Call (301) 443–6634 or send an email to *aherzog@hrsa.gov* if you are having trouble connecting to the meeting site.

Agenda: The agenda items for the December 2014 meeting will include, but are not limited to: updates from the Division of Injury Compensation Programs (DICP), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and the Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (*http://www.hrsa.gov/vaccinecompensation/accv.htm*) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DICP, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857 or email: *aherzog@hrsa.gov.* Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by email, mail, or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the ACCV should contact Annie Herzog, DICP, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–6593, or email: *aherzog@hrsa.gov.*

Dated: November 7, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–27188 Filed 11–14–14; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Heterocyclic Compounds for the Treatment of Hepatitis C Virus

Description of Technology: The vast majority of people infected with Hepatitis C Virus (HCV) will have chronic infection. Over decades, this can lead to liver disease and liver cancer. In fact, HCV infection is the leading cause of liver transplants in the U.S. Several new drugs have recently come into the market that have changed the HCV treatment paradigm. However, the effectiveness of these new drugs can vary depending on the HCV genotype. Furthermore, all oral, interferon free therapeutic regimens for HCV infection will need combinations of drugs that target different aspects of the HCV life cycle. Thus, there is still the need for additional new therapeutics against HCV.

The subject technologies are aryloxazole based small molecules that are potent inhibitors of HCV infection and replication. The compounds exhibit synergy with currently available therapeutics for HCV and represent a new class of anti-HCV compounds. The compounds affect the entry step of HCV infection, a step not targeted by currently available therapeutics against HCV.

Potential Commercial Applications: Prevention and treatment of HCV infection.

Competitive Advantages:

- Potent inhibitors of HCV infection and replication.
- Show synergistic effect with currently available HCV therapeutics.
- Represent new class of HCV inhibitors that target the entry step of HCV infection.

Development Stage:

- Early-stage.
- In vitro data available.