COST OF REGISTRATION *	
ADFO Member	$475.00
Non-ADFO Member	575.00

* A $100 registration fee will be added if payment is postmarked after June 1, 2014.

If you need special accommodations due to a disability, please contact Randy Young (see AFDO Contact information) at least 21 days in advance of the workshop.

Registration instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to ''AFDO.'' Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., Suite 311, York, PA 17402. To register online, please visit *http://www.afdo.org/conference.* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 1–717–757–2888, FAX: 717–650–3650, or email: *afdo@afdo.org.*

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include, but are not limited to the following:

- Medical Device Single Audit Program;
- Contract Manufacturing Arrangements for Drugs: Quality Agreements;
- Compliance Question and Answer Panel;
- Draft Guidance: Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements;
- Compounding Pharmacies;
- Overview of Global Device/Drug Requirements vs. U.S. System;
- Case for Quality Initiative Update;
- Unique Device Identifier Implementation Update;
- Metric, Data, and Analysis; Biometrics;
- Pharmaceutical Inspection Cooperation Scheme; and
- Biosimilar Regulations.

FDA has made education of the food, feed, drug, and device manufacturing community a high priority to help ensure the quality of FDA-regulated products. The public workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

Dated: March 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07059 Filed 3–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Pediatric 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 Committee: Pediatric Advisory Committee.

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

Date and Time: The meeting will be held on April 21, 2014, from 8 a.m. to 5 p.m. This is a reschedule of a postponed meeting announced in the **Federal Register** of January 14, 2014 (79 FR 2452), originally scheduled for March 3, 2014.

Location: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814, 301–897–9400 or visit the hotel's Web site at *http://www.marriott.com/hotels/travel/wasbt-bethesda-marriott/.*

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301–796–0885, email: *walter.ellenberg@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 21, 2014, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155). The PAC will meet to discuss Activa Dystonia Therapy, ADVATE (antihemophilic factor (recombinant)), FAMVIR (famciclovir), INTELENCE (etravirine), KEPPRA (levetiracetam), MAXALT and MAXALT MLT (rizatriptan), NATAZIA (estradiol valerate and estradiol valerate/dienogest), PERTZYE (pancrelipase), PERZISTA (darunavir), REYATAZ (atazanavir), SKLICE (ivermectin), TISSEEL (fibrin sealant), TORISEL (temsirolimus), ULTRESA (pancrelipase), Vertical Expandable Prosthetic Titanium Rib (VEPTR), and VIREAD (tenofovir disoproxil fumarate).

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/AdvisoryCommittees/Calendar/default.htm.* 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 April 14, 2014. Oral presentations from the public will be scheduled on April 21, 2014, between approximately 11:30 a.m. and 12:30 p.m. Those individuals interested in making 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 April 4, 2014. 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 April 7, 2014.

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 Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: March 26, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–07112 Filed 3–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0388]

Determination of Regulatory Review Period for Purposes of Patent Extension; PREVNAR–13

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PREVNAR–13 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA 2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product PREVNAR–13 (Pneumococcal 13-valent conjugate vaccine (diphtheria CRM–197 protein)). PREVNAR–13 is indicated for (1) Active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, in patients aged 6 weeks through 17 years of age and in adults 50 years of age and older; and (2) active immunization for the prevention of otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in patients aged 6 weeks through 5 years. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PREVNAR–13 (U.S. Patent No. 5,614,382) from Wyeth Holdings Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 9, 2012, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of PREVNAR–13 represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PREVNAR–13 is 2,102 days. Of this time, 1,771 days occurred during the testing phase of the regulatory review period, while 331 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* May 26, 2004. The applicant claims April 23, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 26, 2004, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 31, 2009. The applicant claims October 24, 2008, as the date the biologics license application (BLA) for PREVNAR–13 (BLA 125324) was initially submitted. However, FDA records indicate that BLA 125324 was a rolling submission and the final module was received by FDA on March 31, 2009.

3. *The date the application was approved:* February 24, 2010. FDA has verified the applicant's claim that BLA 125324 was approved on February 24, 2010.