FDA estimates the one-time reporting burden for this guidance would be 230,652 hours during the first year for section 904(a)(3) of the FD&C Act reporting plus ongoing annual burden of 11,550 hours for section 904(c)(1) reporting. The burden estimate for this collection of information includes the time it will take to read the guidance document, test the products, and prepare the HPHC report.

To avoid overcounting the one-time reporting burden, FDA has annualized the one-time burden over the 3-year expected OMB period of approval. The annualized one-time burden of 76,884 hours is located in part one of table 1 of this document, and includes burden for collections of information gathered under section 904(a)(3) of the FD&C Act. The total annual burden for this collection of information is estimated to be 88,434 hours, which is the annualized one-time burden estimate for section 904(a)(3) of the FD&C Act associated with the submission of HPHC reports and the annual burden estimate for section 904(c)(1). Table 1 of this document estimates 366 respondents will submit HPHC reports on a one-time basis. Table 1 of this document addresses the time required for manufacturers and importers to report their company information. We estimate that the burden is no more than 2 hours per response to report company and product information, regardless of whether the paper or electronic form (Form FDA 3787) is used. This estimate is not dependent on product type, so the estimated burden is the same for cigarettes, roll-your-own tobacco, and smokeless tobacco products. We also estimate that 3,636 cigarette subbrands, 445 roll-your-own tobacco subbrands, and 861 smokeless tobacco subbrands (4,942 total subbrands) must comply with section 904(a)(3) of the FD&C Act. Therefore, the total annualized burden for reporting company and product information is 3,296 hours.

Table 1 of this document also addresses the time required for manufacturers and importers to report quantities of HPHCs in their products. The burden hour estimates include the time needed to test the tobacco products, draft testing reports, draft the report for FDA, and submit the report to FDA. For cigarette filler, smokeless, and roll-your-own products, we estimate the burden to test the product, draft testing reports, draft the report for FDA, and submit the report to FDA to be 16,284 annualized burden hours. The burden for each product type reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work).

In addition to addressing the time required to report quantities of HPHCs in tobacco products, table 1 of this document addresses the time required for manufacturers and importers to report quantities for HPHCs in cigarette smoke. The burden estimates include testing the tobacco products, drafting testing reports, drafting the report for FDA, and submitting the report to FDA. We estimate the annualized burden for this section to be 57,304 hours. The annualized burden reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to the two recommended smoking regimens. The total annualized burden for part one of table 1 (section 904(a)(3) reporting) is 76,884 hours.

Table 1 of this document also contains estimates for new product information received annually under section 904(c)(1) of the FD&C Act. Manufacturers and importers must report HPHC information under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce. We estimate that approximately 15 percent of FDA currently regulated tobacco products in any given year will require submission of this information. The estimated total annual burden for section 904(c)(1) of the FD&C Act is 11,550 hours, which includes reporting manufacturer/importer company and product information, reporting HPHC quantities in products, and reporting HPHC quantities in mainstream smoke.

The estimated total annual burden for the reporting of HPHC under section 904(a)(3) and (c)(1) of the FD&C Act is 88,434 hours, which includes the section 904(a)(3) annualized reporting burden plus the section 904(c)(1) annual reporting burden.

We have not estimated any capital costs because we do not believe there are any capital costs associated with this collection. However, you may comment on any specific capital costs that you have identified.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18442 Filed 7–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–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 September 11, 2012, from 8:30 a.m. to 4 p.m.

Location: DoubleTree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301–589–5200.

Contact Person: Walter Ellenberg, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD. 20993, 301–796–0885, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 September 11, 2012, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Public Law 107–109) and the Pediatric Research Equity Act (Public Law 108–155), for Kapvay (clonidine hydrochloride), Vyvanse (lisdexamfetamine dimesylate), Ofirmev (acetaminophen), ella (ulipristal acetate), Beyaz (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Lo

Loestrin Fe (norethindrone acetate and ethinyl estradiol ethinyl estradiol and ferrous fumarate), Aridol (mannitol inhalation powder), Augmentin XR (amoxicillin/clavulanate potassium), Afinitor (everolimus), Moxeza (moxifloxacin hydrochloride), and Lastacaft (alcaftadine).

As mandated by the Food and Drug Administration Amendments Act, Title III, Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85), the committee will discuss the safety of and the ongoing propriety of the humanitarian device exemption for the Melody Transcatheter Pulmonary Valve and Ensemble Delivery System and the Elana Surgical Kit.

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 September 4, 2012. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on September 11, 2012. 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 August 24, 2012. 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 August 27, 2012.

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 (*walter.ellenberg@fda.hhs.gov*) or 301–796–0885 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: July 24, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–18509 Filed 7–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Rodent Testing to Identify Pharmacotherapies for Substance Dependence (8908).

Date: August 23, 2012.

Time: 9:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 435–1439, *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 24, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18475 Filed 7–27–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Clinical Trials at the NHLBI.

Date: August 20, 2012.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892–7924, 301–435–0288, *cjoyce@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Pathogen Inactivation for Blood Components.

Date: August 20, 2012.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, *Pintuccig@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases