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 May 7, 2012, from 8 a.m. to 5:30 p.m. and May 8, 2012, from 8:30 a.m. to 11:30 a.m.

Location: Hilton Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Walter Ellenberg, Office of Pediatric Therapeutics, Office of the Commissioner, 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 (301–433–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 7, 2012, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, for Differin Lotion (adapalene), Dulera Inhalation Aerosol (mometasone furoate and formotorol fumarate), MultiHance Injection (gadobenate dimeglumine), Nasonex (mometasone furoate monohydrate), Natazia (estriadiol valerate and estradiol valerate/dienogest), Omnaris Nasal Spray (ciclesonide), Protonix (pantoprazole), Tamiflu (oseltamivir phosphate), Taxotere (docetaxel) and Viread (tenofovir disoproxil fumarate). The Committee will also receive an Informational Update on FDA’s KidNet pilot study.

On May 8, 2012, the Pediatric Advisory Committee will meet regarding the pediatric-focused safety reviews, as mandated by the Pediatric Research Equity Act, for Gardasil Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant, Isospto Carpine (pilocarpine hydrochloride), Menveo Meningococcal (Group A,C,Y, and W–135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine, Zylet (loteprednol etabonate and tobramycin) and Zymaxid (gatifloxacin).

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 or before April 30, 2012. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on May 7, 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 April 20, 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 April 23, 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 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).


Leslie Kux,
Acting Assistant Commissioner for Policy.

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accomplishing reinvention goals is the ability to periodically receive input and feedback from customers about the design and quality of the services they receive.

The NLM provides significant services directly to the public including health providers, researchers, universities, other federal agencies, state and local governments, and to others through a range of mechanisms, including publications, technical assistance, and Web sites. These services are primarily focused on health and medical information dissemination activities. The purpose of this submission is to obtain OMB’s generic approval to continue to conduct satisfaction surveys of NLM’s customers. The NLM will use the information provided by individuals and institutions to identify strengths and weaknesses in current services and to make improvements where feasible. The ability to periodically survey NLM’s customers is essential to continually update and upgrade methods of providing high quality service.

Frequency of Response: Annually or biennially. Affected Public: Individuals or households; businesses or other for profit; state or local governments; Federal agencies; non-profit institutions; small businesses or organizations. 

Type of Respondents: Organizations, medical researchers, physicians and other health care providers, librarians, students, and the general public. The annual reporting burden is as follows:

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<th>Types of respondents</th>
<th>Estimated number of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Estimated total annual burden hours requested</th>
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<tr>
<td>Researchers, Physicians, Other Health Care Providers, Librarians, Students, General Public</td>
<td>15,000</td>
<td>1</td>
<td>.150</td>
<td>2,250</td>
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The annualized cost to respondents for each year of the generic clearance is estimated to be $20,670. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number 301-402-9680 or Email your request to sharlipd@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: March 27, 2012.

David H. Sharlip,
NLM Project Clearance Liaison, National Library of Medicine, National Institutes of Health

[FR Doc. 2012–7831 Filed 3–30–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 Cancer Institute Special Emphasis Panel; Small Grants for Behavioral Research in Cancer Control (R03).

Date: June 7, 2012.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard Room 8059, Bethesda, MD 20892–8329, 301–496–7904, decluej@mail.nih.gov.

Information is also available on the Institute’s/Center’s home page: http://deainfo.nci.nih.gov/advisory/sep/sep.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 27, 2012.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–7824 Filed 3–30–12; 8:45 am]

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