

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and 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 November 26, 2008. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m., and between approximately 3:30 p.m. and 4 p.m. Those desiring to make 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 November 18, 2008. 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 November 19, 2008.

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 AnnMarie Williams, Conference Management Staff, at 240-276-8932, 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/oc/advisory/default.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: October 6, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

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. The committee also advises and makes recommendations to the Secretary under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on Tuesday, November 18, 2008, from 8 a.m. to 5 p.m.

Location: Holiday Inn Gaithersburg, 2 Montgomery Village Rd., Gaithersburg, MD 20877.

Contact Person: Carlos Peña, Office of Science and Health Coordination, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14B-08), Rockville, MD 20857, 301-827-3340, e-mail: carlos.peña@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732310001. 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 November 18, 2008, the Pediatric Advisory Committee will hear and discuss reports by the agency, as mandated in section 17 of the Best Pharmaceuticals for Children Act (BPCA), on adverse event reports for BETOPTIC S (betaxolol), ALDARA (imiquimod), LAMICTAL (lamotrigine), LEVAQUIN (levofloxacin),

SANDOSTATIN (octreotide), ZYPREXA (olanzapine), RISPERDAL (risperidone), LAMISIL (terbinafine), TIMOLOL GFS (timolol), and AMBIEN (zolpidem). The committee will be provided a written followup report on ZYVOX (linezolid), as requested by the committee at the November 16, 2006, Pediatric Advisory Committee meeting. The committee will also be updated on other activities, including the June 9 and 10, 2008, Pediatric Ethics Subcommittee meeting.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and 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 October 27, 2008. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on November 18, 2008. Those desiring to make 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 October 17, 2008. 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 October 20, 2008.

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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/oc/advisory/default.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: October 7, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-24356 Filed 10-14-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee, certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through August 31, 2009.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the

date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nomination for membership should be sent electronically to CV@OC.FDA.GOV, or by mail to Advisory Committee Oversight & Management Staff (HF-4), 5600 Fishers Lane, rm. 15A-12, Rockville, MD 20857. Information about becoming a member on a FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/oc/advisory/default.htm>.

FOR FURTHER INFORMATION CONTACT:

Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 7520 Standish Pl., (MPN1), Rockville, MD 20855, 240-276-8938, e-mail: Kathleen.Walker@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Vacancies

FDA is requesting nominations of voting members for vacancies listed as follows:

TABLE 1.

| Committee/Panel and Expertise Needed | Current & Upcoming Vacancies | Approximate Date Needed |
|---|------------------------------|--------------------------------|
| Dental Products Panel of the Medical Devices Advisory Committee—dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy | 3 | Immediately |
| Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee—experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills | 1 1 | Immediately October 1, 2008 |
| Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee—otologists, neurotologists, audiologists | 3 | November 1, 2008 |
| Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee—transplant specialists, gastroenterologists, urologists, and nephrologists | 3 | January 1, 2009 |
| General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee—surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians | 2 | September 1, 2009 |
| Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee—hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and homeostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers | 2 2 | Immediately March 1, 2009 |
| Immunology Devices Panel of the Medical Devices Advisory Committee—persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine | 1 2 | Immediately March 1, 2009 |