

the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

#### **RETENTION AND DISPOSAL:**

Records are maintained for a period of six years and three months. All claims-related records are encompassed by the document preservation order and will be retained until notification is received by DOJ.

#### **SYSTEM MANAGER AND ADDRESS:**

Director, Division of Ombudsman Casework and Trends Management, Medicare Ombudsman Group, Office of External Affairs, CMS, 7500 Security Boulevard, Mail Stop S1-11-21, Baltimore, Maryland 21244-1850.

#### **NOTIFICATION PROCEDURE:**

For purpose of access, the subject individual health care provider should write to the system manager who will require the system name, National Provider Identifier, address, date of birth, and gender, and for verification purposes, the subject individual health care provider's name (woman's maiden name, if applicable), and Social Security number (SSN). Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

#### **RECORD ACCESS PROCEDURE:**

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a) (2)).

#### **CONTESTING RECORD PROCEDURES:**

The subject individual health care provider should contact the systems manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with department regulation 45 CFR 5b.7).

#### **RECORD SOURCE CATEGORIES:**

The data contained in this system of records are obtained from the individuals who communicate or correspond with CMS.

#### **SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative on the Pediatric Advisory Committee and Request for Nominations for a Nonvoting Industry Representative on the Pediatric Advisory Committee**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on its Pediatric Advisory Committee notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for an upcoming vacancy on June 30, 2008, effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by March 28, 2008, for vacancies listed in this notice. Concurrently, nomination material for prospective candidates should be sent to FDA by March 28, 2008.

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to Carlos Peña (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** 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, or by e-mail: *Carlos.Peña@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The agency requests nominations for a

nonvoting industry representative on the Pediatric Advisory Committee.

#### **I. Function**

The committee advises and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding: (1) Pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act (42 U.S.C. 262, 284m, and 290b) and sections 501, 502, 505, 505A, and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 355a, and 355c); (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric labeling disputes as specified in section 3 of the Best Pharmaceuticals for Children Act (Public Law 107-109); (5) pediatric labeling changes as specified in section 5 of the Best Pharmaceuticals for Children Act; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur as specified in section 17 of the Best Pharmaceuticals for Children Act; (7) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products; (8) research involving children as subjects as specified in 21 CFR 50.54; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The committee also advises and makes recommendations to the Secretary of Health and Human Services (the Secretary) directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

#### **II. Selection Procedure**

Any pediatric products industry, association, or organization interested in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select an industry representative, within 60 days after the receipt of the FDA letter, and the industry

representative will serve as the nonvoting member to represent industry interests for the Pediatric Advisory Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

### III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee (persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

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

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: February 19, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Pediatric Oncology Subcommittee of the Oncologic Drugs 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 Oncology Subcommittee of the Oncologic Drugs 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 16, 2008, from 8:30 a.m. to 3:30 p.m.

*Location:* Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Nicole Vesely, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-6793, FAX: 301-827-6776, e-mail:

*nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. 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:* The subcommittee will consider and discuss opportunities for enhancing global pediatric oncology drug development and expanding international regulatory interactions given the January 2007 legislation introduced in the European Union that governs the development and authorization of medicines for use in children aged 0 to 17 years.

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 subcommittee. Written submissions may be made to the contact person on or before April 2, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 March 25, 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 March 26, 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 Nicole Vesely 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: February 19, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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,