• The Joint Commission developed and conducted surveyor training on CMS documentation requirements to ensure that issues cited provide a clear and detailed description of the deficient practice and relevant finding.

• The Joint Commission modified its policies regarding complaint investigation activities to comply with the requirements at § 488.4(a)(6) and Chapter 5 of the SOM.

• To meet the Medicare requirements related to unannounced surveys at 2700A of the SOM, the Joint Commission modified its electronic application process to no longer allow an ASC to indicate ''avoid dates'' or ''a ready month'' in which organizations could receive an accreditation survey for deemed status.

• The Joint Commission revised its accreditation decision letters to ensure they are accurate and contain all the required elements necessary for the CMS Regional Office to render a decision regarding deemed status of a provider.

• The Joint Commission modified its policies regarding condition-level noncompliance identified during an initial certification survey for participation in Medicare in accordance with section 2005A of the SOM.

• To meet the requirements at § 416.41, the Joint Commission revised its standards to require that patients in Medicare-certified ASC that require emergency treatment beyond the capability of the ASC be transferred to local hospitals that meet requirements for payment of emergency services.

• To meet the requirements at § 416.44(a)(2), the Joint Commission revised its standards to require Medicare certified ASCs to provide a separate waiting area and post-anesthesia room.

• To meet the requirements at § 416.44(b)(1) and § 416.44(b)(5), § 416.45(a), and § 416.48(a), the Joint Commission amended its Medicare crosswalk to reflect current regulatory language.

• To meet the requirements at § 416.45, the Joint Commission added a standard requiring Medicare-certified ASCs to ensure that licensed independent practitioners are accountable to the governing body.

• To meet the requirements at § 416.45(b), the Joint Commission added a standard requiring Medicare-certified ASCs to periodically review and amend the scope of procedures performed.

• To meet the requirements at § 416.48, the Joint Commission added a new standard requiring Medicare-certified ASCs to designate one individual responsible for pharmaceutical services.

• To meet the requirements at § 416.49, the Joint Commission added a standard requiring Medicare-certified ASCs to comply with 42 CFR part 493 which requires organizations who perform laboratory testing to maintain compliance with Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that the Joint Commission's requirements for ASCs meet or exceed our requirements. Therefore, we approve the Joint Commission as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2008 through December 20, 2014.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: October 2, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–27120 Filed 11–13–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0578]

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 of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services (DHHS), when that research is also regulated by the FDA.

Date and Time: The meeting will be held on Tuesday, December 9, 2008, from 3:30 p.m. to 6 p.m.

Location: The Legacy Hotel & Meeting Centre, 1775 Rockville Pike, Rockville, MD 20852.

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, or by 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 December 9, 2008, the Pediatric Advisory Committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on December 9, 2008, regarding a referral by an Institutional Review Board of a clinical investigation that involves both an FDA-regulated product and research involving children as subjects that is conducted or supported by DHHS.

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 December 2, 2008. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on December 9, 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 November 24, 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 25, 2008.

Electronic comments should be submitted to *http://www.regulations.gov*. Select Docket No. FDA–2008–N–0578 entitled ''G–CSF Stimulated Bone Marrow IRB Referral'' and follow the prompts to submit your statement. Written comments should be submitted to Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please submit comments by 4:30 p.m. on December 2, 2008. Received comments may be viewed at *http://www.regulations.gov*, or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 Carlos Peña 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: November 5, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–27117 Filed 11–13–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0578]

Pediatric Ethics Subcommittee; 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 Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA, and certain Department of Health and Human Services (DHHS) regulatory issues.

Date and Time: The meeting will be held on Tuesday, December 9, 2008, from 9 a.m. to 3 p.m.

Location: The Legacy Hotel & Meeting Centre, 1775 Rockville Pike, Rockville, MD 20852.

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, or by 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 December 9, 2008, the Pediatric Ethics Subcommittee (subcommittee) of the Pediatric Advisory Committee will meet to discuss a referral by an Institutional Review Board (IRB) of a clinical investigation that involves both an FDA regulated product and research involving children as subjects that is conducted or supported by DHHS. The clinical investigation is entitled ''Children's Oncology Group Protocol ASCT0631: A Phase III Randomized Trial of Granulocyte Colony Stimulating Factor (G–CSF) Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation.'' Because the clinical investigation would be regulated by FDA, and conducted or supported by the DHHS, both FDA and the Office for Human Research Protections, DHHS, will participate in the meeting.

After presentation of an overview of the IRB referral process, background information on the use of G–CSF stimulated bone marrow in stem cell transplantation, an overview of the protocol and the referring IRB's deliberations on the protocol, and a summary of public comments received concerning whether the protocol should proceed, the subcommittee will discuss the proposed protocol and develop a recommendation regarding whether the protocol should proceed. The subcommittee's recommendation will then be presented to the FDA Pediatric Advisory Committee on December 9, 2008; the announcement of the December 9, 2008, Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

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 December 2, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 9, 2008. Those desiring to make formal oral presentations should notify the contact