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

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 submited 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 the 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.

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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. E8–27118 Filed 11–13–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Nursing Scholarship Program (NSP): Extension—(OMB No. 0915–0301)

The Nursing Scholarship Program (NSP) or ''Nursing Scholarship'' is a competitive Federal program which awards scholarships to individuals for attendance at schools of nursing. The program is administered by the Bureau of Clinician Recruitment and Service (BCRS) in HRSA. The scholarship consists of payment of tuition, fees, other reasonable educational costs, and a monthly support stipend. In return, the students agree to provide a minimum of 2 years of full-time clinical service (or an equivalent part-time commitment, as approved by the NSP) at a health care facility with a critical shortage of nurses as defined by the program.

Nursing scholarship recipients must be willing and are required to fulfill their NSP service commitment at a health care facility with a critical shortage of nurses in the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Territory of Guam, the Commonwealth of the Northern Marianas, the U.S. Virgin Islands, the Territory of America Samoa, the Republic of Palau, the Republic of the Marshall Islands, or the Federated States of Micronesia. Students who are uncertain of their commitment to provide nursing in a health care facility with a critical shortage of nurses in the United States and its Territories are advised not to participate in this program.

The NSP needs to collect data to determine an applicant's eligibility for the program, to monitor a participant's continued enrollment in a school of nursing, to monitor the participant's compliance with the NSP service obligation, and to obtain data on its program to ensure compliance with legislative mandates and prepare annual reports to Congress. The following information will be collected: (1) From the applicants and/or the schools, general applicant and nursing school data such as full name, location, tuition/fees, and enrollment status; (2) from the schools, on an annual basis, data concerning tuition/fees and student enrollment status; and (3) from the participants and their health care facilities with a critical shortage of nurses, on a biannual basis, data concerning the participant's employment status, work schedule and leave usage. The BCRS enters the cost information into its computerized data system, along with the projected amount for the monthly stipend, to determine the amount of each scholarship award.

The estimated annual burden is as follows:

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Application	4,000	1	4,000	2	8,000
In-school monitoring	500	1	500	2	1,000