DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

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 November 2, 2011, from 8 a.m. to 3:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, The Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Bldg. 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533. e-mail: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 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 November 2, 2011, the subcommittee will consider and discuss regulatory, academic, and industry perspectives regarding the development of anticoagulant products (products to suppress clotting of blood) in children. Issues for discussion will include identification of strategies to encourage and facilitate studies of anticoagulants in children that will result in informative pediatric labeling, appropriate endpoints for studies of anticoagulants in pediatric patients, and the role of pharmacokinetic/pharmacodynamic studies to support a pediatric indication of the approximate time requested to make their presentation on or before October 11, 2011. 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 12, 2011.

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 Caleb Briggs 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/default.htm; under the heading “Advisory Committees,” scroll down to the appropriate advisory committee link.

Proposed Collection; Comment Request; Cancer Risk in U.S. Radiologic Technologists: Fourth Survey (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of
the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Cancer Risk in U.S. Radiologic Technologists: Fourth Survey (NCI). Type of Information Collection Request: Reinstatement with change of a previously approved collection (OMB No. 0925–0405, expiration 02/28/2011). Need and Use of Information Collection: By conducting a fourth cohort follow-up survey in an ongoing cohort study of U.S. Radiologic Technologists (USRT), updated information will be collected on cancer and other medical outcomes, personal medical radiation procedures, and other risk factors from all participants, plus detailed employment data from subgroups of participants who performed or assisted with fluoroscopically-guided or radioisotope procedures. Researchers at the National Cancer Institute and The University of Minnesota have followed a nationwide cohort of 146,000 radiologic technologists since 1982, of whom 110,000 completed at least one of three prior questionnaire surveys and 23,454 are deceased. This cohort is unique because estimates of cumulative radiation dose to specific organs (e.g. breast) are available and the cohort is largely female, offering a rare opportunity to study effects of low-dose radiation exposure on breast and thyroid cancers, the two most sensitive organ sites for radiation carcinogenesis in women. The fourth survey will be administered by mail to approximately 93,000 living and located cohort members who completed at least one of the three previous surveys to collect information on new cancers and other disease outcomes, detailed work patterns and practices from technologists who worked with radioisotopes and interventional radiography procedures, and new or updated risk factors that may influence health risks. New occupational and medical radiation exposure information will be used to improve radiation dose estimates. The annual reporting burden is reported in Table 1. 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 are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functioning of the National Cancer Institute, including whether the information will have practical utility; (2) 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) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to 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 additional information on the proposed collection of information contact: Michele M. Doody, Radiation Epidemiology Branch, National Cancer Institute, Executive Plaza South, Room 7051, Bethesda, MD 20892–7238, or call non-toll-free at 301–594–7203. You may also e-mail your request to doodym@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 this publication.

Dated: September 15, 2011.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Institute of Environmental Health Sciences Special Emphasis Panel, Superfund Hazardous Substance Research and Training Program.

Date: October 11–12, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Raleigh-Durham Airport Hotel, 4810 Page Creek Lane, Durham, NC 27703.

Contact Person: Janice B. Allen, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Science, P. O. Box 12233, MD EC–30/Room 3170 B, Research Triangle Park, NC 27709, (919) 541–7556.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Human Health Effects Of