noting the safety and effectiveness of therapeutics. To reach optimal decisions, regulators will often use a risk analysis that involves a deliberative process of risk management, risk communication and risk assessment. The workshop aims to increase the transparency of the decision-making process at FDA by increasing public understanding of risk assessment in the regulatory process for blood products. Risk assessment is a process that reflects a structured approach of hazard identification, hazard characterization, exposure assessment and risk characterization. The QRA public workshop is designed to enhance understanding of the agency’s operations and decision-making process in this regard. The workshop will discuss the principles of risk assessment, and a detailed case study using a recent risk assessment related to blood safety and availability will be presented.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at http://www.fda.gov/ BiologicsBloodVaccines/NewsEvents/ WorkshopsMeetingsConferences/ TranscriptsMinutes/default.htm.


Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

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 meeting.

The meeting 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: Virtual Consortium for Transdisciplinary/Translational Environmental Research (VICTER).

Date: May 26, 2010.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 26, 2010, 11 a.m. to May 26, 2010, 2 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the Federal Register on April 21, 2010, 75 FR 20852–20853.

The meeting title has been changed to “Meeting Conflict: Cancer Biomarker.” The meeting is closed to the public.


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

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