suite 200N, Rockville, MD 20852–1448, 301–827–6129, *FAX:* 301–827–2843, *e-mail: rhonda.dawson@fda.hhs.gov.*

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person (*see Contact Person*) by November 19, 2010. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (*see CONTACT PERSON*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Severe bleeding may be encountered in both traumatic and non-traumatic clinical situations. New products for the treatment of severe bleeding are needed to reduce the need for blood transfusions, minimize complications resulting from blood loss, and improve patient outcomes. The development and approval of new products for use in treatment of severe bleeding, particularly severe bleeding resulting from trauma, has been complicated by the lack of a consensus definition of severe bleeding as well as the need to identify appropriate clinical endpoints for assessment of product safety and efficacy. Clinical endpoints may vary depending on the product indications, patient characteristics, nature of injury, whether the product acts locally or systemically, the nature of the product (*e.g.,* device, drug, biologic, or combination), and conditions of use.

Because it may not always be feasible to obtain standard informed consent, clinical trials of products used for the treatment of life-threatening severe bleeding resulting from trauma may raise significant ethical and legal considerations. Researchers studying products for use in such circumstances may need guidance to carry out appropriate consultation with representatives of the communities in which the clinical investigation will be conducted and from which the study participants will be selected. Clinical trials on products intended for use in trauma are also complicated by the difficulty of identifying patients who may meet study inclusion criteria. Given these challenges, further discussion is needed about how products approved for use for treatment of severe bleeding occurring during surgery or due to non-surgical conditions may best be evaluated for use in treatment of severe bleeding in trauma.

The first day of the workshop will include presentations and panel discussions on the following topics: (1) Current clinical scientific knowledge concerning the pathophysiology of trauma and assessment of severe bleeding; (2) currently available locally acting and systemic products used to treat severe bleeding in trauma and non-trauma settings; (3) animal models for pre-clinical evaluation of products; (4) ethical considerations for clinical trials to evaluate products used in treatment of severe bleeding in trauma; and (5) clinical evaluation of products for bleeding interventions, including clinical trials and endpoints. The second day of the workshop will include a discussion of whether products with an indication for use in severe bleeding due to trauma can be evaluated in clinical settings other than a trauma clinical trial and a summary of the sessions presented at the workshop.

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.*

Dated: *October 13, 2010.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–26212 Filed 10–18–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 materials, 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 Neurological Disorders and Stroke Special Emphasis Panel, SPOTRIAS.

Date: December 15, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call.)

Contact Person: Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Room 3208, MSC 9529, Bethesda, MD 20892–9529. 301–496–0635. *Rc218u@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 13, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–26321 Filed 10–18–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Medicinal Chemistry.

Date: November 9–10, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.