rheumatology collaborative networks, such as the Childhood Arthritis and Rheumatology Research Alliance or the Pediatric Rheumatology Collaborative Study Group.

5. Define, for phase 4 studies in JIA patients, the database standards and elements of data collection (e.g., data quality, monitoring) that are necessary and sufficient to meet FDA regulatory requirements.

6. Discuss how pertinent research initiatives can be accomplished in the framework of a consolidated JIA registry, including:

- Ethical considerations.
- Data sharing considerations.

7. Discuss the options for funding a consolidated JIA registry.

B. Issues for Comment

FDA is interested in obtaining public comment on the following issues relating to development of a consolidated pediatric rheumatology observational registry:

1. Should we transition from product-specific registries to a consolidated pediatric rheumatology observational registry?

2. Currently, the product-specific registries are conducted by the individual sponsors of the approved drugs and/or biological products with the safety data submitted to FDA.

- How should a consolidated pediatric rheumatology observational registry be structured to collect data and conduct analyses to meet the standards for postmarketing requirements set by FDA and provide information about long-term safety?
- What hurdles must be overcome to transition from product-specific registries to a consolidated pediatric rheumatology observational registry (e.g., industry concerns, pediatric rheumatology community concerns, proprietary issues of longer term data and informed consent, fulfilling FDA regulatory requirements, challenges of registry funding, management and ownership or sharing of data)?

3. What data should be collected in a consolidated pediatric rheumatology observational registry? Consider the following topics:

Database standards and terminology (e.g., compatibility with large databases).

Necessary and sufficient data elements (e.g., safety, effectiveness, growth and development, comorbidities, tracking medication switches over time, as well as concurrent medication).

Length of individual patients' participation and overall duration of the consolidated pediatric rheumatology observational registry (e.g., managing pediatric data through and beyond the age of consent).

4. What are the optimal methods to analyze data from a consolidated pediatric rheumatology observational registry to identify safety signals? For example, should the methods define risk windows for attribution to a drug or biological product; internal controls; and/or analyses of confounding by indication, switches in medication, and multiple concurrent medications?

5. What are the opportunities for research initiatives within a consolidated observational rheumatology registry?

III. Attendance and Registration to Speak

There is no fee to attend the workshop, and attendees who do not wish to make an oral presentation do not need to register. Seating will be on a first-come, first-served basis.

If you would like to make an oral presentation during the open public session on day one of the workshop, you must register and provide an abstract of your presentation by close of business on April 21, 2009. To speak, submit your name, title, business affiliation (if applicable), address, telephone and fax numbers, and e-mail address to Diane Ehrlich (see **FOR FURTHER INFORMATION CONTACT**). FDA has included questions for comment in section II of this document. You should also identify by number each question you wish to address in your presentation, and the approximate time requested for your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make an oral presentation should check in before the workshop.

Ample time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage written comments to the docket. Written or electronic comments will be accepted until July 14, 2009.

If you need special accommodations because of disability, please contact Diane Ehrlich (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

IV. Comments

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by July 14, 2009 (see **DATES**). Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcript

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available 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.

Dated: March 19, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6709 Filed 3–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Gestational Diabetes Life-Course Study.

Date: April 20, 2009.

Time: 2 p.m. to 3:30 p.m.

Agenda: To provide concept review of proposed concept review.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680. *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 20, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–6786 Filed 3–25–09; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Neurological Disorders and Stroke Special Emphasis Panel. Mutiple System Atrophy.

Date: April 7, 2009.

Time: 2 p.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: Ernest W Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529. 301–496–4056. *lyonse@ninds.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel. Stroke Trial.

Date: April 14, 2009.

Time: 1 p.m. to 3 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., Suite 3208, MSC 9529, Bethesda, MD 20892–9529. 301–594–0635. *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: March 19, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–6660 Filed 3–25–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering; NACBIB May 2009.

Date: May 15, 2009.

Time: 8:30 a.m. to 11:45 a.m.

Agenda: Report from the Institute Director, other Institute Staff and presentations of working group reports.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Closed: 12:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Anthony Demsey, PhD, Director, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Blvd., Room 241, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nibib1.nih.gov/about/NACBIB/NACBIB.htm*, where an agenda and any additional information for the meeting will be posted when available.

Dated: March 20, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–6784 Filed 3–25–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the PubMed Central National Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: PubMed Central National Advisory Committee.

Date: June 15, 2009.

Time: 8:30 a.m. to 3 p.m.

Agenda: Review and Analysis of Systems.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: David J. Lipman, MD, Director, Natl Ctr for Biotechnology Information, National Library of Medicine, Building 38, Room 8N805, Bethesda, MD