implemented through a retail pharmacy system.

a. What are the advantages and disadvantages of the various models of drug distribution under a REMS?

b. Should sponsors be permitted to choose the drug distribution system they prefer to manage the risks, or should a common distribution system be employed for REMS?

6. Can implementation of elements to assure safe use be standardized (e.g., could uniform systems for providing prescriber and pharmacist education or certification be developed)?

a. Is there a preferred way to standardize the elements to assure safe use (e.g., based on the nature of the risk, across a class of drugs with common risks, or around certain elements such as prescriber education or pharmacy certification)?

b. What are the advantages and disadvantages of standardizing the way elements to assure safe use are implemented on:

i. Patient safety?

ii. Patient access?

D. Evaluating the Effectiveness of REMS

1. How should REMS be monitored and assessed to determine their effectiveness, considering the different types of REMS elements (e.g., Medication Guides, communication plans, elements to assure safe use)?

2. How should the overall burden on the health care system of a REMS with elements to assure safe use be monitored and assessed, considering the different types of elements to assure safe use (e.g., training or certification of prescribers and pharmacists, implementation of patient registries)?

3. Should metrics for determining the effectiveness of a REMS be specified at the time the REMS is approved? How should the appropriate metrics be determined?

4. Are surveys the optimal method to assess patient and health care provider understanding of the serious risks and safe use of the drug? Are there alternative methods that should be considered?

E. Effects of REMS on Generic Drugs

1. Section 505–1(f)(8) states that no holder of an approved application shall use any element to assure safe use required by the Secretary to block or delay approval of an application under section 505(b)(2) or (j) or to prevent application of an element to assure safe use to a drug that is the subject of an abbreviated new drug application. What steps should FDA take to ensure that REMS are not used to block or delay generic competition?

2. FDAAA requires that innovator and generic sponsors use a single shared system to provide a REMS with elements to assure safe use, unless a waiver is granted. What design or process features should be taken into account when designing an innovator REMS to facilitate use of a single shared system when generics are approved?

F. Protection of Patient Information

1. Some REMS with elements to assure safe use require enrollment of patients and health care providers in a program, or require a patient registry as a condition of prescribing or dispensing a drug.

a. What, if any, privacy concerns are raised by these programs?

b. Does enrollment in a REMS program or a patient registry without requiring a specific collection of health information raise the same privacy concerns?

2. What steps should FDA take to reduce concerns about patient privacy when REMS with such elements to assure safe use are determined to be necessary to ensure the benefits of a drug outweigh its risks?

V. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first come, first served basis. Individuals who wish to present at the public meeting must register by email to *REMSpublicmeeting@fda.hhs.gov* on or before June 30, 2010, and provide complete contact information, including name, title, affiliation, address, email, and phone number. In section IV of this document, FDA has included questions for comment. You should identify by number each question you wish to address in your presentation, so that FDA can consider that in organizing the presentations. FDA will do its best to accommodate requests to speak, and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. An agenda will be available approximately 2 weeks before the meeting on the Agency Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm210201.htm.*

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

A live Web cast of this meeting will be available on the Agency Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm210201.htm* on the day of the meeting. A video record of the meeting will be available at the same Web address for 1 year.

VI. Comments

Regardless of attendance at the public meeting, 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 are to be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by August 31, 2010. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the meeting. A transcript will also be made available in either hard copy or on CD-ROM, upon 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: June 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–14547 Filed 6–11–10; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, Clinical Hematology,

Date: June 25, 2010,

Time: 4:30 p.m. to 7 p.m.,

Agenda: To review and evaluate grant applications,

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Delia Tang, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7802, Bethesda, MD 20892, 301–435–2506, *tangd@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 10, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–14640 Filed 6–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, Human Protein Affinity Reagents.

Date: June 22, 2010.

Time: 4 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard A. Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Electromagnetic Devices.

Date: June 22, 2010.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Antonio Sastre, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5215, MSC 7412, Bethesda, MD 20892, 301–435–2592, *sastrea@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 10, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–14643 Filed 6–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 material, 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 Child Health and Human Development Special Emphasis Panel; Data Archive on Adolescent Pregnancy and Pregnancy Prevention.

Date: July 7, 2010.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6100 Executive Boulevard, 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: June 11, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–14645 Filed 6–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, RFA–OD–10–005 Director's Opportunity 5 Themes Oral Musculoskeletal and Imaging.

Date: June 28, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jean D Sipe, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4106, MSC 7814, Bethesda, MD 20892. 301/435–1743. *sipej@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing