not being pursued for this technology): ''Deletion of Lysogeny Genes and Toxin Genes from Bacteriophage Used in the Epidemiologic Control of Bacterial Illness.''

HHS Reference No. E–179–1996— Research Materials (patent protection is not being pursued for this technology): ''Therapeutics Use of Phage Expressing Toxin-Binding and/or Cytokine-Binding Proteins and Elimination of Genes Associate with Lysogeny.''

HHS Reference No. E–196–1997— Research Materials (patent protection is not being pursued for this technology): ''Antibacterial Therapy with Bacteriophage Genotypically Modified to Delay Inactivation by the Host Defense System.''

HHS Reference Nos. E–089–1998 and E–257–2003—Research Materials (patent protection is not being pursued for this technology): ''Two Enterocin-Producing Strains of Bacteria and Their Enterocins, Both of Which Are Lethal to Vancomycin-Resistant *Enterococcus faecium.''*

HHS Reference No. E–012–1999— Research Materials (patent protection is not being pursued for this technology): ''Long Circulating Phage Vectors.''

Licensing Status: Technologies are available for licensing, either individually or as a package.

Licensing Contact: Bruce Goldstein, J.D., M.S.; 301–435–5470; *goldsteb@mail.nih.gov.*

Collaborative Research Opportunity: The NCI Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: September 1, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–21787 Filed 9–9–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0392]

Medical Devices: Neurological Devices; Electroconvulsive Therapy Device; Establishing a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a public docket to receive information and comments regarding the current classification process related to electroconvulsive therapy devices (ECT). The current classification process for this device pertains to the ''Order for Certain Class III Devices; Submission of Safety and Effectiveness,'' published in the **Federal Register** of April 9, 2009 (74 FR 16214). Under the Order, FDA required manufacturers of certain Class III devices, including ECT, to submit a summary of, and citation to, any information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information which has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). For each device subject to the Order, FDA is reviewing the submitted information to determine whether FDA should maintain the device as class III and require the submission of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP), or whether FDA should reclassify the device into class II or class I. FDA is now inviting interested persons to submit comments that relate to the safety and effectiveness of ECT.

DATES: Submit written or electronic comments and information by January 8, 2010.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and information to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Victor Krauthamer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., W066–1106, Silver Spring, MD 20993, 301–796–2474.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 9, 2009 (74 FR 16214), FDA published an ''Order for Certain Class III Devices; Submission of Safety and Effectiveness Information'' (''515(i) Order''). Under this Order, as mandated by section 515(i) of the act (21 U.S.C. 360e(i)), FDA required manufacturers of certain class III devices that were in commercial distribution before May 28, 1976, and devices found to be substantially equivalent to them that were marketed on or after that date, including ECT, to submit to FDA by August 7, 2009, a summary of, and citation to, any information known, or otherwise available to them respecting those devices including, adverse safety or effectiveness data that had not been submitted under section 519 of the act (21 U.S.C. 360i). In addition, manufacturers were encouraged by FDA to submit a summary of the information previously sent to FDA under section 519 of the act. Currently, the agency is in the process of reviewing the information that has been submitted by the manufacturers subject to the 515(i) Order.

Based upon the review of this submitted information, FDA is considering whether to issue a proposed rule requiring the device to remain in class III, followed by the issuance of a regulation requiring submission of a PMA or PDP, or to revise the classification of the devices into class II, requiring the designation of special controls, or into class I, requiring only general controls. In determining whether to revise the classification of a device, or to require a device to remain in class III, FDA will apply the criteria set forth in section 513(a) of the act. If FDA decides to reclassify the device, FDA must determine that general controls alone (class I) or general controls plus special controls (class II) would provide reasonable assurance of the safety and effectiveness of the device. FDA's proposed classification of ECT devices will be subject to notice and comment rulemaking to allow for additional public comment.

FDA has received a significant number of inquiries from members of the public and the health care community in response to this order to ECT manufacturers. In recognition of this significant public interest, FDA is opening this docket to permit individuals other than manufacturers to submit information related to the safety and effectiveness of ECT. If individuals wish to report an adverse event associated with the use of an ECT device, please use the MedWatch Online Voluntary Reporting Form available at *https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm*. FDA will review information submitted through the MedWatch program prior to making any changes to the classification of ECT devices.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 24, 2009.

Catherine M. Cook,

Associate Director for Regulations and Policy.

[FR Doc. E9–21807 Filed 9–9–09; 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 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 Child Health and Human Development Special Emphasis Panel; GO Grants-2.

Date: September 15, 2009.

Time: 2 p.m. to 6 p.m.

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

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Marita R. Hopmann, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hopmannm@mail.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. 93.864, 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: September 1, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–21771 Filed 9–9–09; 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 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 Child Health and Human Development Initial Review Group; Developmental Biology Subcommittee.

Date: October 5–6, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, 1515 Rhode Island Ave, NW., Washington, DC 20005.

Contact Person: Norman Chang, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health And Human Development, NIH, 6100 Executive Blvd., Room 5b01, Bethesda, MD 20892, (301) 496–1485, *changn@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: September 1, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–21776 Filed 9–9–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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 Human Genome Research Institute Initial Review Group; Genome Research Review Committee.

Date: November 5–6, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ken D. Nakamura, PhD, Scientific Review Officer, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301 402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: September 1, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–21773 Filed 9–9–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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,