

## I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the

applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2010, through June 30, 2010. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2010, THROUGH JUNE 30, 2010

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P090018 FDA-2010-M-0244	Envoy Medical Corp.	ESTEEM TOTALLY IMPLANTABLE HEARING SYSTEM	March 17, 2010
P080029 FDA-2010-M-0220	Interventional Therapies, LLC	QUICK CLOSE VASCULAR SUTURING SYSTEM	April 8, 2010
P090022 FDA-2010-M-0219	Lenstec, Inc.	SOFTEC HD POSTERIOR CHAMBER INTRA-OCULAR LENS (PCIOL)	April 12, 2010
P080032 FDA-2010-0242	Asthmatix, Inc.	ALAIR BRONCHIAL THERMOPLASTY	April 27, 2010
P090007 FDA-2010-M-0261	Roche Diagnostics Corp.	ELECSYS ANTI-HCV IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HCV FOR USE ON THE COBAS E411 IMMUNOASSAY ANALYZER	April 29, 2010
P090008 FDA-2010-M-0262	Roche Diagnostics Corp.	ELECSYS ANTI-HCV IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HCV FOR USE ON THE COBAS E601 IMMUNOASSAY ANALYZER	April 29, 2010
P090009 FDA-2010-M-0264	Roche Diagnostics Corp.	ELECSYS ANTI-HCV IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HCV FOR USE ON THE MODULAR ANALYTICS E170 ANALYZER	April 29, 2010
P050027 FDA-2010-M-0294	Karl Storz endoscopy—America, Inc.	PHOTODYNAMIC DIAGNOSTIC D-LIGHT C	May 28, 2010
P060029 FDA-2010-M-0285	Ethicon, Inc.	OMNEX SURGICAL SEALANT	June 3, 2010

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: August 31, 2010.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2010-22085 Filed 9-2-10; 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 and 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; Review of T32 Applications on Clinical and Developmental Pharmacology.

*Date:* September 29, 2010.

*Time:* 1 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Sathasiva B. Kandasamy, 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, 301-435-6680, [skandasa@mail.nih.gov](mailto: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: August 30, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-22087 Filed 9-2-10; 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, 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 on Aging Initial Review Group, Neuroscience of Aging Review Committee.

*Date:* October 4-5, 2010.

*Time:* 4 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20892.

*Contact Person:* William Cruce, PhD, Scientific Review Administrator, National Institute on Aging, Scientific Review Office, Gateway Building 2C-212, 7201 Wisconsin

Ave., Bethesda, MD 20814, 301-402-7704, [crucew@nia.nih.gov](mailto:crucew@nia.nih.gov).

*Name of Committee:* National Institute on Aging Initial Review Group, Clinical Aging Review Committee.

*Date:* October 7-8, 2010.

*Time:* 7 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20892.

*Contact Person:* Alicja L. Markowska, PhD, DSC, National Institute On Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, [markowska@nia.nih.gov](mailto:markowska@nia.nih.gov).

*Name of Committee:* National Institute on Aging Initial Review Group, Biological Aging Review Committee.

*Date:* October 7, 2010.

*Time:* 12 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Bitu Nakhai, PhD., Scientific Review Officer, Scientific Review Branch, National Institute On Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301-402-7701, [nakhaib@nia.nih.gov](mailto:nakhaib@nia.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 27, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-22089 Filed 9-2-10; 8:45 am]

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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 Language and Communication Study Section, October 4, 2010, 8 a.m. to October 5, 2010, 5 p.m., Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037 which was published in the **Federal Register** on August 25, 2010, 75 FR 52357.

The meeting will be one day only October 4, 2010. The meeting time and location remain the same. The meeting is closed to the public.

Dated: August 26, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-22090 Filed 9-2-10; 8:45 am]

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## 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:* Oncology 2—Translational Clinical Integrated Review Group, Basic Mechanisms of Cancer Therapeutics Study Section.

*Date:* October 4-5, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Marina del Rey Hotel, 13534 Bali Way, Marina del Rey, CA 90292.

*Contact Person:* Lambratu Rahman, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301-451-3493, [rahman@csr.nih.gov](mailto:rahman@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group, Clinical Research and Field Studies of Infectious Diseases Study Section.

*Date:* October 7-8, 2010.

*Time:* 8:30 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

*Contact Person:* Soheyla Saadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301-435-0903, [saadisoh@csr.nih.gov](mailto:saadisoh@csr.nih.gov).

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group, Clinical Oncology Study Section.

*Date:* October 11-12, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Long Beach and Executive Meeting Center, 701 West Ocean Boulevard, Long Beach, CA 90831.

*Contact Person:* Malaya Chatterjee, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301-451-0131, [chatterm@csr.nih.gov](mailto:chatterm@csr.nih.gov).