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.

II. Electronic Access

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


Nancy K. Stade,
Deputy Director for Policy, Center for Devices and Radiological Health.

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.

Table 1.—List of Safety and Effectiveness Summaries for Approved PMAs Made Available from April 1, 2010, through June 30, 2010

<table>
<thead>
<tr>
<th>PMA No.</th>
<th>Docket No.</th>
<th>Applicant</th>
<th>TRADE NAME</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>P090018</td>
<td>FDA–2010–M–0244</td>
<td>Envoy Medical Corp.</td>
<td>ESTEEM TOTALLY IMPLANTABLE HEARING SYSTEM</td>
<td>March 17, 2010</td>
</tr>
<tr>
<td>P080029</td>
<td>FDA–2010–M–0220</td>
<td>Interventional Therapies, LLC</td>
<td>QUICK CLOSE VASCULAR SUTURING SYSTEM</td>
<td>April 8, 2010</td>
</tr>
<tr>
<td>P090022</td>
<td>FDA–2010–M–0219</td>
<td>Lenstec, Inc.</td>
<td>SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS (PCIOL)</td>
<td>April 12, 2010</td>
</tr>
<tr>
<td>P080032</td>
<td>FDA–2010–0242</td>
<td>Asthmatic, Inc.</td>
<td>ALAIR BRONCHIAL THERMOPLASTY</td>
<td>April 27, 2010</td>
</tr>
<tr>
<td>P090007</td>
<td>FDA–2010–M–0261</td>
<td>Roche Diagnostics Corp.</td>
<td>ELECSYS ANTI-HCV IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HCV FOR USE ON THE COBAS E411 IMMUNOASSAY ANALYZER</td>
<td>April 29, 2010</td>
</tr>
<tr>
<td>P060029</td>
<td>FDA–2010–M–0285</td>
<td>Ethicon, Inc.</td>
<td>OMNEX SURGICAL SEALANT</td>
<td>June 3, 2010</td>
</tr>
</tbody>
</table>
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, 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, 2701 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, PhD, Scientific Review Officer, Scientific Review Branch, National Institute On Aging, Gateway Blvd., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7701, nakhabi@nia.nih.gov.

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


Jennifer S. Spaeth, Director, Office of Federal Advisory Committee Policy.

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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, rahmanl@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, saadish@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, 707 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, 301–451–0111, chatterm@csr.nih.gov.