**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2011–N–0332]

**Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice of availability that appeared in the Federal Register on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. The August 4, 2011, notice is the Agency’s report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct. The document was published with an error. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:**


**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011–19806, appearing on page 47211 in the Federal Register of August 4, 2011, the following correction is made:

On page 47214, table 1 is corrected to read as follows:

**TABLE 1—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS**

<table>
<thead>
<tr>
<th>NDA/ANDA (% of Total PMR or % of total PMC)</th>
<th>BLA (% of Total PMR or % of total PMC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of open PMRs</td>
<td>526</td>
</tr>
<tr>
<td>On-schedule open PMRs (see table 2 of this document)</td>
<td>477 (91%)</td>
</tr>
<tr>
<td>Off-schedule open PMRs (see table 3 of this document)</td>
<td>49 (9%)</td>
</tr>
<tr>
<td>Number of open PMCs</td>
<td>473</td>
</tr>
<tr>
<td>On-schedule open PMCs (see table 4 of this document)</td>
<td>399 (84%)</td>
</tr>
<tr>
<td>Off-schedule open PMCs (see table 5 of this document)</td>
<td>74 (16%)</td>
</tr>
<tr>
<td>On October 1, 2003, FDA completed a consolidation of certain therapeutic products formerly regulated by CBER into CDER. Consequently, CDER now reviews many BLAs. Fiscal year statistics for postmarketing requirements and commitments for BLAs reviewed by CDER are included in BLA totals in this table.</td>
<td></td>
</tr>
<tr>
<td>The number of PMCs reported as open as of September 30, 2009, in the “Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments” notice published in the Federal Register on November 9, 2010 (75 FR 68902), inadvertently also included open PMRs. That error has been corrected for the current reporting period.</td>
<td></td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

2011 Technology Transfer Summit North America Conference

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice of Conference.

SUMMARY: The NIH Office of Technology Transfer extends invitations to attend the 2011 Technology Transfer Summit North America Conference.

DATES: October 3–4, 2011.

ADDRESS: NIH campus, 9000 Rockville Pike, Bethesda MD, NIH Clinical Center (Building 10), Masur Auditorium.

SUPPLEMENTARY INFORMATION: The NIH campus in Bethesda, MD will be the site for the 2011 Tech Transfer Summit North America (TTSNA), the leading early-stage biotech partnering, licensing, venture and innovation platform, co-hosted and co-sponsored by the NIH Office of Technology Transfer, TTS Ltd. and regional host partners such as BIO Maryland.

TTSNA is one of a series of summits held within the Global Tech Transfer Initiative and is designed specifically to put innovators, early-stage SMEs and technology managers from leading universities and research institutes together with biotech & pharma licensing & business development executives, VCs, serial entrepreneurs, and leading IP specialists for interactive sessions relating to partnering, licensing & business development.

Conference speakers for the 2011 include:

—Kathy Hudson, Deputy Director, National Institutes of Health (NIH)
—James C. Greenwood, President & CEO, BIO
—Shiv Krishnan, Director, Scouting & Partnering, Sanofi, USA
—Sanjeet Munshi, Director, Licensing and External Research, Merck & Co
—David Kaslow, Head of Vaccines Project & Pipeline Leadership, Merck & Co
—Ed Mascioli, Head of Orphan & Genetic Diseases Research Unit, Pfizer
—Arthur Tzianabos, Vice President of Research, HGTV Division, Shire
—Steve Groff, Director, Office of Rare Diseases Research, NIH
—Phil Ross, Managing Director, Healthcare, JPMorgan
—Maarten de Jong, Managing Director, Barclays Capital
—Andrew Robertson, Chief Policy Officer, BIO Ventures for Global Health
—Orin Herskowitz, Executive Director & Vice President, Intellectual Property Technology Transfer, Columbia Technology Ventures
—Erik Lium, Assistant Vice Chancellor of Research, UCSF
—Brian Kelly, Director, Technology, Enterprise & Commercialisation, Weil Cornell Medical College
—Daniel Perez, Partner, Bay City Capital
—Hubert Birner, Partner, TVM Capital
—Glen Steinbach, COO, Johns Hopkins Technology Transfer
—Markus Goebel, Managing Director, Novartis Venture Fund

The Summit will strive to induce interactive debate, deliberation and discussion, networking and business over the 2-day period with the leaders in the sector. The Summit conference will be further enhanced by the TTS Initiative Business Social Network, an online business-networking platform powered by JuJaMa. The Network is a communication tool for business that will allow the posting of profiles and technology offers; the searching of other participants by category, by technology or licensing offer; and the setting up of meetings prior to, during and after the Summit. Total participation numbers for this conference will be strictly limited to ensure the ideal environment for real discussion and business.

FOR FURTHER INFORMATION CONTACT: More details about the conference including registration information and the conference agenda can be found by contacting Tech Transfer Summit North America (http://www.techtransfersummit.com/northamerica2011). Attendees may also enter the Partner Code “NIH11” to register with a 10% reduction. For information about sign language interpretation or accommodation for disabilities, please contact Sharon Fields at telephone 301–594–7700 or fieldssh@od.nih.gov.

Dated: August 16, 2011.

Steven M. Ferguson,
Deputy Director, Licensing & Entrepreneurship, Office of Technology Transfer, National Institutes of Health.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases 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 Allergy and Infectious Diseases Special Emphasis Panel; Targeting Resistance in Select Gram-Negative Pathogens.

Date: September 22–23, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Silver Spring, 8727 Colesville Road, Chesapeake Room, Silver Spring, MD 20910.

Contact Person: Nancy Lewis Ernst, PhD, Scientific Review Official, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–493–7103, nancy.ernst@nih.gov.

Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS.

Dated: August 17, 2011.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

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