

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Pulse Oximeters—Premarket Notification Submissions [510(k)s]," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (1605) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. 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. Received 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: July 3, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7-14012 Filed 7-18-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Mice Genetically Deficient in the Chemoattractant Receptor FPR (Formyl Peptide Receptor)

Description of Invention: The present research tool is a knockout mouse model (FPR^{-/-}) that lacks the high affinity N-formylpeptide receptor (FPR), created by targeted gene disruption.

N-formylpeptides derive from bacterial and mitochondrial proteins, and bind to specific receptors on mammalian phagocytes. Since binding induces chemotaxis and activation of phagocytes *in vitro*, it has been postulated that N-formylpeptide receptor signaling *in vivo* may be important in antibacterial host defense, although direct proof has been lacking. The inventors have found that FPR^{-/-} mice have no obvious developmental defects and do not develop spontaneous infection when derived in specific

pathogen-free conditions. This suggests that, under these conditions, FPR is dispensable. However, when challenged with *L. monocytogenes*, FPR-deficient mice have accelerated mortality and increased bacterial burden in liver and spleen early after infection, which suggests a role for FPR in host defense, specifically through regulation of innate immunity.

Applications and Modality: New mouse model to study antibacterial host defense.

Market: Research tool useful for innate immunity studies.

Development Status: The technology is a research tool.

Inventors: Philip Murphy and Ji-Liang Gao (NIAID).

Patent Status: HHS Reference No. E-258-2007/0—Research Tool.

Publication: JL Gao, EJ Lee, PM Murphy. Impaired antibacterial host defense in mice lacking the N-formylpeptide receptor. *J Exp Med.* 1999 Feb 15;189(4):657-662.

Licensing Status: This technology is not patented. The mouse model will be transferred through a Biological Materials License.

Licensing Contact: Peter J. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Collaborative Research Opportunity: The Laboratory of Molecular Immunology, NIAID, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize FPR knockout mice. Please contact Philip Murphy, M.D. at Tel: 301-496-8616 and/or pmm@nih.gov for more information.

Steroid Derivatives as Inhibitors of Human Tyrosyl-DNA Phosphodiesterase (Tdp1)

Description of Technology: Tyrosyl-DNA phosphodiesterase (Tdp1) is an enzyme that repairs topoisomerase I (Top1)-mediated DNA damage induced by chemotherapeutic agents and ubiquitous DNA lesions that interfere with transcription. The current technology are steroid derivatives that human inhibit Tdp1.

Currently, there are various types of Top1 inhibitors used in chemotherapy, e.g., camptothecin. However, Tdp1 inhibitors are expected to be effective in combination therapy with Top1 inhibitors for the treatment of cancers. Combining Tdp1 inhibitors with Top1 inhibitors would allow Tdp1 to potentiate the antiproliferative activity of Top1 inhibitors. In addition to Tdp1's effect on Top1, Tdp1 inhibitors can also exhibit antitumor activity independently, as tumors are shown to

have excess free radicals, and Tdp1 repairs DNA damage by oxygen radicals.

Applications and Modality: It is anticipated that Tdp1 inhibitors in association with Top1 inhibitors can have selective activity toward tumor tissues. Tdp1 inhibitors may exhibit antitumor activity by themselves because tumors have excess free radicals.

Market: 600,000 deaths from cancer related diseases were estimated in 2006. In 2006, cancer drug sales were estimated to be \$25 billion.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Yves Pommier *et al.* (NCI).

Relevant Publication: A manuscript directly related to the above technology will be available as soon as it is accepted for publication.

Patent Status: U.S. Provisional Application No. 60/921,980 filed 05 Apr 2007 (HHS Reference No. E-130-2007/0-US-01).

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Adaku Nwachukwu, J.D.; 301/435-5560; madua@mail.nih.gov.

Collaborative Research Opportunity: The Center for Cancer Research, National Cancer Institute, Laboratory of Molecular Pharmacology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize inhibitors of Tyrosyl-DNA phosphodiesterase (Tdp1). Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: July 9, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-13955 Filed 7-18-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 552(b)(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 Mental Health Special Emphasis Panel, Expedited Review of Tornado Survivors PTSD.

Date: July 31, 2007.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Allan F. Mirsky, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Rm. 6157, MSC 9609, Bethesda, MD 20892-9609, 301-496-2551, afmirsky@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: July 9, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-3507 Filed 7-18-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel, Pathogenesis of NeuroAIDS and Alcohol Use (RFA-AA-07-015).

Date: August 7, 2007.

Time: 1:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Abraham P. Bautista, PhD, Chief, Extramural Project Branch Review, National Institute on Alcohol Abuse & Alcoholism, National Institutes of Health, 5635 Fishers Lane, RM 3039, Rockville, MD 20852, 301-443-9737, bautistaa@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: July 9, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-3508 Filed 7-18-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel, Review of Specialized and Comprehensive Alcohol Research Centers (RFA-AA-07-002; AA-02-003).

Date: August 2, 2007.

Time: 1:30 p.m. to 5 p.m.