interests to participate in meetings where we conclude, after close scrutiny, that certain criteria are met. (See 18 U.S.C. 208(b)(1) and (b)(3) and section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (added by the Food and Drug Administration Amendments Act of 2007 (Public Law No. 110–85), section 701 (effective October 1, 2007).)

In the **Federal Register** of January 12, 2002 (67 FR 6545), FDA issued ''Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees,'' and requested comments on the draft guidance (Docket No. 02D–0049). The draft guidance was limited in application to special government employees (SGEs) participating in advisory committee meetings at which particular matters relating to particular products were discussed.

FDA has recently undertaken an internal assessment of its advisory committee process. As a result of this review, and based on the comments submitted to the docket for the January 2002 draft guidance, FDA is revising this draft guidance to broaden its applicability, bring as much transparency as possible to FDA's waiver process, and increase the consistency and clarity of the process. The draft guidance proposes revised procedures, consistent with section 712(c)(3) of the act, to make publicly available relevant information regarding financial interests and waivers granted by the agency for SGEs and regular Government employees invited to participate in FDA advisory committee meetings.

The draft guidance also includes a template for disclosing to the public the disqualifying financial interests for which waivers are sought and a template for all waivers that FDA grants. The guidance further describes FDA's process for making these documents available on its Web site in advance of each advisory committee meeting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on public availability of information regarding advisory committee members' financial interests and waivers granted by FDA to permit participation in advisory committee meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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: October 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–5408 Filed 10–29–07; 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.

Immunostimulatory Combinations of TLR Ligands and Methods of Use

Description of Technology: New drugs or therapies that act by stimulating the immune system, or alternatively inhibiting certain aspects of the immune system, may be useful for treating various diseases or disorders, for example viral diseases, neoplasias, and/or allergies, and may also have use as vaccine adjuvants. However, although adjuvants have been suggested for use in vaccine compositions, there is an unmet need for adjuvants that can effectively enhance immune response.

Development of innate and adaptive immunity critically depends on the engagement of pattern recognition receptors (PRRs), which specifically detect microbial components named pathogen- or microbe-associated molecular patterns (PAMPs or MAMPs) (1–4). Toll-like receptors (TLRs) represent an important group of PRRs that can sense PAMPs or MAMPs once in the body. TLRs are widely expressed by many types of cells, for example cells in the blood, spleen, lung, muscle and intestines.

The present invention claims immunostimulatory combinations of TLR ligands and therapeutic and/or prophylactic methods that include administering an immunostimulatory combination to a subject. In general, the immunostimulatory combinations can provide an increased immune response compared to other immunostimulatory combinations and/or compositions. More specifically, combinations of TLR 2, 3 and 9 are claimed. The application also describes a novel mechanism for TLR synergy in terms of both signaling pathways and cytokine combinations.

Application: Development of improved adjuvants and/or synergistic combinations of adjuvants for vaccines.

Developmental Status: Compositions have been synthesized and preclinical studies have been performed.

Inventors: Jay Berzofsky and Qing Zhu (NCI).

Patent Status: U.S. Provisional Application filed 24 Sep 2007 (HHS Reference No. E–298–2007/0–US–01).

Licensing Status: Available for exclusive or nonexclusive licensing.

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

Collaborative Research Opportunity: The National Cancer Institute's Vaccine Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this invention of synergistic combinations of TLR ligands. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Cellular Receptor for Varicella-Zoster Virus, Methods of Inhibiting Spread of Varicella-Zoster and Methods of Increasing Stability and Infectivity of the Virus

Description of Technology: This technology relates to identification of insulin degrading enzyme (IDE) as a cellular receptor for Varicella-Zoster-Virus (VZV), the etiologic agent of varicella (chickenpox) and zoster (shingles). Acute infection of VZV is followed by cell-associated viremia and the development of varicella rash. The virus establishes life-long latency in the nervous system and can reactivate to cause zoster. The mechanism of VZV entry into target cells and spread from cell-to-cell is not well understood. The inventors have shown that antibodies to IDE and soluble IDE partially inhibit infection with the virus in cell culture. Reducing the level of IDE in the cell (with siRNA), or blocking the ability of IDE to bind with a VZV glycoprotein, markedly diminishes cell-to-cell spread of the virus in cell culture and partially inhibits infection of cells with cell-free virus. This invention further describes molecules that may have a role in the treatment or prevention of VZV infections, including antibodies to IDE, peptides that block IDE-VZV interactions, and other molecules that block binding activity of IDE.

Applications: Treatment and prevention of varicella zoster virus infection.

Market: Prophylactics and therapeutics for chickenpox and shingles.

Development Status: Early-stage technology.

Inventors: Jeffery Cohen and Qingxue Li (NIAID).

Patent Status: U.S. Provisional Application No. 60/684,526 filed 26 May 2005 (HHS Reference No. E–289–2004/0–US–01); PCT Application No. PCT/US2006/020514 filed 26 May 2006 (HHS Reference No. E–289–2004/0–PCT–02).

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

Licensing Contact: Chekesha S. Clingman, PhD; 301/435–5018; *clingmac@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases, Medical Virology Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. Jeffrey Cohen at *jcohen@niaid.nih.gov* for more information.

An HIV Protein for Use as a Novel Therapeutic or Vaccine Component

Description of Technology: Latent HIV presents a challenge for complete removal of the virus in infected individuals and is becoming an increasingly important consideration in the identification of potential HIV therapeutics or treatment regimens. These transcriptionally inactive HIV reservoirs lay dormant in a portion of infected cells and are capable of evading both host defenses and existing antiretroviral therapy. The present technology offers a potential solution for complete eradication of HIV in infected individuals.

This technology describes immunogenic and therapeutic compositions related to HIV p28TEV protein, the first protein expressed during HIV infection in the case of the pHXB2 isolate. p28TEV functions in the regulation of HIV transcription and may be important for the expression of latent virus. A number of p28TEV associated compositions are available for licensing and commercial development including: (1) The p28TEV polypeptide from one or more HIV clades, (2) nucleic acids encoding these p28TEV polypeptides, (3) a polypeptide with significant sequence homology to p28TEV, and (4) immunogenic fragments of these polypeptides. Additional compositions include antibodies and antagonists that act to inhibit p28TEV activity. Adjuvants, immunomodulators and compounds used in combination with p28 TEV for the treatment of HIV infection are also included in the available technology.

Applications: Novel therapeutics for treatment of HIV infection; Novel HIV vaccine component.

Development Status: Preclinical data are available at this time.

Inventors: Genoveffa Franchini *et al.* (NCI).

Patent Status: U.S. Patent Application No. 11/364,873 filed 27 Feb 2006 (HHS Reference No. E–072–2004/3–US–01); PCT Application No. PCT/US2007/0004694 filed 23 Feb 2007, which published as WO 2007/098257 on 30 Aug 2007 (HHS Reference No. E–072–2004/4–PCT–01).

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

Licensing Contact: Susan Ano, PhD; 301/435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Vaccine Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Methods of Targeting the Establishment of the HIV Viral Reservoir. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Methods for Identifying Cathepsin G-Related Peptides as Modulators of Formylpeptide Receptors

Description of Technology: Available for licensing and commercial development are methods for identifying peptides of Cathepsin G (CaG), or active variants thereof, which modulate activities of the receptor for bacterial chemotactic formyl peptides (FPR), including chemotactic behavior. It provides methods of designing therapeutic approaches related to the host defense based on the interaction of CaG and FPR, as CaG binds to FPR to mediate the proinflammatory activities of CaG. The inventive aspects relate to the finding that CaG induces a more partial and selective effects upon activation of FPR to mediate a certain and more limited immunological activity than other agonists that are also capable of binding FPR. The limitations in the activity include not inducing calcium flux, having only a weak activation of mitogen-activated protein kinases (MAPKs), and being able to activate certain types of atypical protein kinase C (PKC), such as PKCξ, while not activating PKCα and PKCβ. These limitations are advantageous in attempting to limit the response in mobilizing the phagocytic leukocyte infiltration to mediate the clearance and repair of damaged tissue while not amplifying the general inflammatory response, which may result in damage to healthy and normal tissue.

Applications: Identification of peptides of Cathepsin G that activate certain types of atypical protein kinase C, such as PKCξ, while not activating PKCα and PKCβ, to limit the response in mobilizing the phagocytic leukocyte infiltration while not amplifying the general inflammatory response.

Inventors: Ji Ming Wang, Ronghua Sun, Joost Oppenheim, Ye Zhou (NCI).

Relevant Publication: R Sun *et al.* Identification of neutrophil granule protein cathepsin G as a novel chemotactic agonist for the G protein-coupled formyl peptide receptor. J Immunol. 2004 Jul 1;173(1):428–436.

Patent Status: U.S. Patent Application No. 11/154,744 filed 17 Jun 2005, entitled ''Cathepsin G-Related Peptides as Modulators of Formylpeptide Receptors (FPR),'' published as U.S. 20060008891 (HHS Reference No. E–281–2003/2–US–01).

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

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301/435–4507; *thalhamc@mail.nih.gov.*

Dated: October 24, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–21370 Filed 10–30–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Systemic Lupus Erythematosus Study.

Date: November 14, 2007.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, 800, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Michael L. Bloom, PhD, MBA., Scientific Review Administrator, EP Review Branch, NIH/NIAMS, One Democracy Plaza, Room 820, MSC 4872, 6701 Democracy Blvd, Bethesda, MD 20892–4872, 301–594–4953, *Michael_Bloom@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. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 24, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5391 Filed 10–30–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute On Drug Abuse; 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 Drug Abuse Special Emphasis Panel, I/START Review.

Date: November 9, 2007.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Virtual Meeting)

Contact Person: Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 200, Bethesda, MD 20892–8401, (301) 435–1389, *ms80x@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. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 24, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5392 Filed 10–30–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

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 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 of Mental Health Special Emphasis Panel, Depression and Stroke.

Date: October 30, 2007.

Time: 3 p.m. to 4 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: David J. Sommers, PhD, Scientific Review Administration, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Social Phobia Treatment.

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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Social Phobia Treatment.

Date: November 5, 2007.

Time: 11 a.m. to 12 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: David J. Sommers, PhD, Scientific Review Administration, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@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. 93.242, 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)