

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-17038 Filed 8-28-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Documents for Comment

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: This is a Notice of Availability and request for comments on draft Agency Guidance ("Policy Information Notices" (PINs)) to describe the policy and processes pertaining to requests from federally-funded health centers to change the scope of their Federal project. The PINs, "Defining Scope of Project and Policy for Requesting Changes," "Change in Scope Requests: Policy for Adding a New Target Population," and "Specialty Services and Health Centers' Scope of Project," are available on the Internet at <http://bphc.hrsa.gov>.

DATES: Comments must be received by September 28, 2007.

ADDRESSES: Please send your comments to the following e-mail address: DPDgeneral@hrsa.gov.

SUMMARY: HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Health Center Program. Therefore, we are requesting comments on the PINs referenced above. After review and consideration of all comments received, the PINs may be amended to incorporate recommendations from the public. Once the PINs are finalized, they will be made available on HRSA's Web site, along with the Agency's "Response to Public Comments." The "Response to Public Comments" will summarize the major comments received and describe the Agency's response, including any corresponding changes made to the PINs. Where comments do not result in a revision to the PINs, explanations will be provided.

Background: HRSA administers the Health Center Program, which supports more than 3,800 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers.

Health centers serve clients that are primarily low-income and minorities, and deliver preventive and primary care services to patients regardless of their ability to pay. Charges for health care services are set according to income. The purpose of the recently published draft PINs is to describe the policy and processes pertaining to requests from federally-funded health centers to change the scope of their Federal project, including requests to include new specialty services and/or a new target population within the scope of the Federal project.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301-594-4300.

Dated: August 21, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7-17092 Filed 8-28-07; 8:45 am]

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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.

Collagen-Induced Platelet Aggregation Inhibitor From Mosquito Salivary Glands

Description of Technology: Exposed collagen in injured blood vessels

provides a substrate for platelets to adhere and aggregate initiating the first step in thrombosis, the formation of blood clots inside a blood vessel. Despite the essential role of platelets in vascular injury, excessive platelet aggregation may also result in thrombotic diseases such as stroke and heart attack.

Available for licensing is a collagen binding protein, named aegyptin, which selectively inhibits collagen-platelet aggregation, but not platelet aggregation induced by other agonists. Collagen initiates recruitment of circulating platelets and triggers platelet activation. Collagen also plays a critical role in angiogenesis. Aegyptin blocks the interaction of collagen with its major ligands, von Willebrand factor, glycoprotein VI (GPVI), and integrin $\alpha 2\beta 1$. These three ligands are of particular importance because von Willebrand factor plays a critical role in tethering platelets to collagen, GPVI is the major signaling platelet receptor, and integrin $\alpha 2\beta 1$ mediates platelet adhesion and contributes to activation. Since these ligands play a critical role in the early stages of thrombus formation, aegyptin represents a potentially highly effective therapeutic that can prevent and treat patients with thrombotic disease. Alternatively, aegyptin is potentially useful in conditions where collagen plays a critical role in angiogenesis or in conditions where excessive deposition of collagen plays a pathological role (e.g. pancreatic carcinoma).

Applications:

Adjuvant to "Clot busting" therapeutics.

Method to prevent and/or treat cardiovascular/thrombotic disease.

Method to treat patients undergoing invasive cardiovascular procedures (e.g. angioplasty).

Model to study collagen-dependent platelet aggregation or collagen-mediated angiogenesis.

Advantages:

Highly effective therapeutics can negatively modulate thrombosis in its early stages by preventing collagen interaction with three major ligands involved in thrombus/clot formation.

Aegyptin's potential use as a prototype for drug delivery as an oral therapeutic, which can reduce the need for invasive surgeries that dilate blood vessels such as stents or catheters.

Market:

Thrombolytic/antithrombotic therapies are worth billions of dollars, common therapeutics include heparin, warfarin, and plasminogen activators.

Anticancer and antiangiogenic therapies.

Cardiac disease is the number one cause of death in the U.S.

Pancreatic cancer is one of the most lethal cancers, where only 23% patients will survive after one year of diagnosis, and 4% survive after five years of diagnosis.

An estimated 37,170 Americans will be newly diagnosed with pancreatic cancer in 2007.

An estimated 33,370 deaths from pancreatic cancer in the U.S. in 2007.

Pancreatic cancer is the fourth leading cause of cancer death in the U.S.

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

Inventors: Eric Calvo *et al.* (NIAID).

Related Publications:

1. A manuscript directly related to this technology will be available as soon as it is accepted for publication.

2. E Calvo. Collagen-platelet aggregation inhibitor from mosquito salivary glands. Biacore T100 seminar series, November 2006, St. Louis, Missouri.

3. S Yoshida and H Watanabe. Robust salivary gland-specific transgene expression in *Anopheles stephensi* mosquito. *Insect Mol Biol.* 2006 Aug;15(4):403-410.

4. D Sun *et al.* Expression of functional recombinant mosquito salivary apyrase: A potential therapeutic platelet aggregation inhibitor. *Platelets.* 2006 May;17(3):178-184.

Patent Status: U.S. Provisional Application No. 60/198,629 filed 09 Jul 2007 (HHS Reference No. E-172-2007/0-US-01).

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

Licensing Contact: Jennifer Wong; 301/435-4633; wongje@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Malaria and Vector Research, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the platelet aggregation inhibitor Aegyptin. Please contact Dr. Jose Ribeiro, Head, Vector Biology Section, at 301-496-9389 or jribeiro@niaid.nih.gov for more information.

Bifunctional Compounds That Bind to Hormone Receptors

Description of Technology: The development and progression of prostate cancer is dependent on the androgen receptor (AR), a ligand-dependent transcription factor. In the inactive form AR resides in the cytosolic region of the cell and when activated, AR is imported into the nucleus. Initial

hormonal therapy for prostate cancer involves lowering serum levels of testosterone to shut down AR activity.

Despite initial patient responses to testosterone-depleting therapies, prostate cancer becomes refractory to hormonal therapy. Notably, AR is reactivated in hormone-refractory prostate cancer and reinstates its proliferative and survival activity.

Available for licensing is a novel chemical compound which is bifunctional and binds to AR. This compound is comprised of tubulin-binding and steroid receptor-binding moieties. This compound is designed to antagonize AR function in a nonclassical manner by several mechanisms and kills hormone-refractory prostate cells better than both functional moieties. This compound is a first-in-class of bifunctional steroid receptor binding agents that can antagonize steroid receptors in a variety of hormone-dependent diseases, such as breast and prostate cancer.

Applications:

Therapeutic compounds that selectively target steroid receptor-expressing cancer cells resulting in decreased toxicity.

Method to treat hormone resistant prostate cancer and potentially other steroid receptor dependent diseases such as breast cancer.

Market:

Prostate cancer is the second most common type of cancer among men, wherein one in six men will be diagnosed with prostate cancer.

An estimated 218,890 new cases of prostate cancer and 27,050 deaths due to prostate cancer in the U.S. in 2007.

An estimated 180,510 new cases of breast cancer and 40,060 deaths due to breast cancer in the U.S. in 2007.

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

Inventors: Nima Sharifi *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 60/958,351 filed 03 Jul 2007 (HHS Reference No. E-163-2007/0-US-01).

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

Licensing Contact: Jennifer Wong; 301 435-4633; wongje@mail.nih.gov

Collaborative Research Opportunity: The Medical Oncology Branch, National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize treatments of resistant prostate cancer. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Specific Binding Agents for KSHV vIL-6 That Neutralize a Biological Activity

Description of Technology: Kaposi's sarcoma-associated herpes virus (KSHV) is an oncogenic herpes virus originally identified in AIDS associated Kaposi's sarcoma (KS) lesions, the most common tumor associated with HIV infection. KSHV encodes various proteins that have characteristics associated with cellular growth and transformation, including viral (v) IL-6 (KSHV vIL-6). These viral proteins display structural homology to their cellular counterparts, and human and vIL-6 are multifunctional cytokines that have been shown to induce vascular endothelial growth factor and other factors.

Available for licensing are binding agents that neutralize vIL-6 biological activities, methods of diagnosing and treating KSHV disorders, and methods to monitor KSHV patient response to treatment. Deregulation of cellular IL-6 expression is known to contribute to tumor development, suggesting that KSHV-derived vIL-6 could be part of a viral strategy to promote malignant transformation. Neutralizing activity of anti-vIL-6 antibodies may provide a potential therapeutic for KSHV disorders such as HIV, Castleman's disease, and primary effusion lymphoma.

Applications:

Therapeutic compositions to treat KSHV disorders such as KS, Castleman's disease, and primary effusion lymphoma.

Method to diagnose and treat KSHV disorders.

Method to monitor patient response to KSHV treatment.

Market:

Approximately 476,095 persons currently living with HIV/AIDS in the United States.

Estimated annual incidence rate for KS is 5 cases per 100,000/year in the U.S.; KS contributes to approximately 30% of AIDS related deaths.

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

Inventors: Giovanna Tosato (NCI) *et al.*

Publications:

1. Y Aoki and G Tosato. Therapeutic options for human herpesvirus-8/Kaposi's sarcoma-associated herpesvirus-related disorders. *Expert Rev Anti Ther.* 2004 Apr;2(2):213-225.

2. Y Aoki *et al.* Detection of viral interleukin-6 in Kaposi sarcoma-associated herpesvirus-linked disorders. *Blood.* 2001 Apr 1;97(7):2173-2176.

3. Y Aoki *et al.* Kaposi's sarcoma-associated herpesvirus-encoded interleukin-6. *J Hematother Stem Cell Res.* 2000;9(2):137-145.

Patent Status:

U.S. Patent No. 6,939,547 issued 06 Sep 2005 (HHS Reference No. E-180-2000/0-US-03).

U.S. Patent No. 7,108,981 issued 19 Sep 2006 (HHS Reference No. E-180-2000/0-US-04).

U.S. Patent No. 7,235,365 issued 26 Jun 2007 (HHS Reference No. E-180-2000/0-US-05).

U.S. Patent Application No. 11/803,732 filed 14 May 2007 (HHS Reference No. E-180-2000/0-US-06).

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

Licensing Contact: Jennifer Wong; 301-435-4633; wongje@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute's Laboratory of Cellular Oncology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize therapeutics for Kaposi's sarcoma-associated herpes virus (KSHV). Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Interferon Alpha Hybrids

Description of Technology: Available for licensing are hybrid interferon alpha (INF- α) polypeptides constructed by combinations of INF α 21b and INF α 2c, and mutants of these hybrids. These hybrid constructs have resulted in novel IFNs that either combine different biological properties from the parent proteins or have significantly different biological activity from both the parents in anti-proliferative, anti-viral, or competitive binding properties. For instance, the hybrid designated HY-3 has higher anti-proliferative activity in Daudi, WISH, and primary human lymphocyte cells exhibiting approximately 6 times higher anti-proliferative activity than either parent IFN. These IFN hybrids provide a powerful tool for studying the structure-function relationship of these molecules. The engineered IFN- α proteins may have important new therapeutic applications and may provide greater insights into understanding of the clinical activities of existing IFN- α s.

Also available for licensing are hybrid INF- α nucleic acids encoding the hybrid polypeptides as well as cells, vectors, pharmaceutical compositions with these nucleic acid sequences.

Applications:

Anti-viral and cancer therapeutics.

Research tool to study IFN- α functions.

Market:

Interferon alpha market was worth \$2.1 billion in 2005.

Industry focus is novel subtype or interferon alpha variants with improved pharmacodynamic and safety properties.

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

Inventors: Kathryn C. Zoon *et al.* (FDA).

Publications:

1. R Hu *et al.* Protein engineering of interferon alphas. *Methods Mol Med.* 2005;116:69-80.

2. R Hu *et al.* Human IFN-alpha protein engineering: The amino acid residues at positions 86 and 90 are important for antiproliferative activity. *J Immunol.* 2001 Aug 1;167(3):1482-1489.

3. Hu *et al.* Divergence of binding, signaling, and biological responses to recombinant human hybrid IFN. *J Immunol.* 1999 Jul 15;163(2):854-860.

Patent Status:

U.S. Patent No. 7,235,232 issued 26 Jun 2007 (HHS Reference No. E-068-1998/0-US-04)

U.S. Patent No. 6,685,933 issued 03 Feb 2004 (HHS Reference No. E-068-1998/0-US-03).

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

Licensing Contact: Jennifer Wong; 301/435-4633; wongje@mail.nih.gov.

Dated: August 20, 2007.

Steven M. Ferguson,

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

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BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the

requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use. This collection was modified during the 60-day comment period to change the annual burden hours from ten to twelve. This change will capture the increase in burden hour and cost to respondents.

Title: Approval and Coordination of Requirements to use the NETC for Extracurricular Training Activities.

OMB Number: 1660-0029.

Abstract: The National Emergency Training Center (NETC) is a FEMA facility, which houses all FEMA employees in headquarters, regions, field establishments, and other individuals and organizations authorized to use the facility, which provides training and educational programs in emergency response, preparedness, fire prevention and control, disaster response, and long-term disaster recovery.

Affected Public: State, Local or Tribal Government, Individuals or households, Business or other for-profit, Not-for-profit institutions, Farms, and Federal Government.

Number of Respondents: 60.

Estimated Time per Respondent: FEMA Form 75-10, 6 minutes and FEMA Form 75-11, 6 minutes.

Estimated Total Annual Burden Hours: 12 minutes.

Frequency of Response: On occasion.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Nathan Lesser, Desk Officer, Department of Homeland Security/FEMA, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-6974. Comments must be submitted on or before September 28, 2007.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Chief, Records Management, FEMA, 500 C Street, SW., Room 609, Washington, DC 20472, facsimile number (202) 646-3347, or e-mail address FEMA-Information-Collections@dhs.gov.