a deeming organization for HHAs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of The Joint Commission's application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of The Joint Commission's (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of The Joint Commission's HHA accreditation standards to our current Medicare HHA conditions for participation.
- A documentation review of The Joint Commission's survey processes to:

++ Determine the composition of the survey team, surveyor qualifications, and the ability of The Joint Commission to provide continuing surveyor training.

++ Compare The Joint Commission's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ Evaluate The Joint Commission's procedures for monitoring providers or suppliers found to be out of compliance with The Joint Commission program requirements. The monitoring procedures are used only when The Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

++ Assess The Joint Commission's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ Establish The Joint Commission's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of The Joint Commission's survey process.

++ Determine the adequacy of staff and other resources.

++ Review The Joint Commission's ability to provide adequate funding for performing required surveys.

++ Confirm The Joint Commission's policies with respect to whether surveys are announced or unannounced.

++ Obtain The Joint Commission's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(b)(3)(A) of the Act, the October 26, 2007 proposed notice (72 FR 60855) also solicited public comments regarding whether The Joint Commission's requirements met or exceeded the Medicare conditions of participation for HHAs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the Joint Commission's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards contained in The Joint Commission's Comprehensive Accreditation Manual for Home Care and its survey process in The Joint Commission's Application for Continued Home Health Deeming Authority with the Medicare HHA conditions for participation and our State Operations Manual (SOM). Our review and evaluation of The Joint Commission's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements for initial home health certification surveys listed in the SOM at 2200A5, The Joint Commission revised its standards to reflect the requirement that HHAs must have provided care to a minimum of ten patients and at least seven of the ten patients are receiving care at the time of the initial survey.
- To meet the requirements for initial certification surveys listed in the SOM at 2200A5, The Joint Commission revised it standards to reflect the requirement that HHAs must provide nursing and at least one other therapeutic service.
- To meet the requirements listed in the SOM at 2200C4, The Joint Commission updated its home care surveyor activity guide to reflect that all patients (private pay and Medicare beneficiaries) are included in the clinical record review or selection of home visits for a Medicare certification survey.
- To meet the requirements of § 488.28(a), The Joint Commission will no longer issue supplemental findings for HHAs seeking deemed status. All deficiencies identified during a certification survey will be cited as requirements for improvement which the HHA will be required to submit a written plan of correction.
- To meet the requirements at 488.8(a)(3), The Joint Commission has agreed to provide CMS with a copy of its most current accreditation survey along with any other related information that CMS requires, including corrected action plans, when requested.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that The Joint Commission's requirements for HHAs meet or exceed our requirements. Therefore, we approve The Joint Commission as a national accreditation organization for HHAs that request participation in the Medicare program, effective March 31, 2008 through March 31, 2014.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: January 25, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–5074 Filed 3–27–08; 8:45 am]

BILLING CODE 4120–01–P

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.

Cell Line PE, Developed From Mouse Skin Tumors, Demonstrates Unique Qualities

Description of Technology: Available for licensing is the mouse skin tumor cell line PE. These skin tumor cells were isolated from papilloma cells induced by chemical carcinogens. The PE cell lines differ from normal keratinocytes in their ability to maintain a proliferating population under conditions favoring terminal differentiation, their consistent proliferative response to phorbol esters under these same conditions, and their reduced sensitivity to phorbol ester-induced terminal differentiation. All of these properties should provide a growth advantage to these cells during tumor promotion. The PE cell line is one of the studied cell lines.

Applications: The PE cell lines could be used for assays for cancer treatment and prevention or study of several aspects of cutaneous biology.

PE cells could be used in the cosmetic industry to study response to cosmaceuticals or fragrances.

PE cells also demonstrated robust expression of phase 2 detoxification enzymes in response to a variety of inducing agents.

Advantage: The various properties of papilloma cells (PE cell line) differ from keratinocytes which will provide a growth advantage to the PE cell lines during tumor promotion.

Market: In the U.S., there was an estimated 59,940 new cases of melanoma cancer in 2007 and an estimated 8,110 melanoma deaths in 2007. There were nearly one million cases of non-melanoma skin cancers diagnosed in the U.S. in 2007.

Cosmetics industry is a $30 billion industry with a 20% annual growth rate.

Inventors: Stuart H. Yuspa and Henry Hennings (NCI).

Publication: SH Yuspa *et al.* Cultivation and characterization of cells derived from mouse skin papillomas induced by an initiation-promotion protocol. Carcinogenesis 1986 Jun;7(6):949–958.

Patent Status: HHS Reference No. E–100–2008/0—Research Tool. Patent protection is not being sought for this technology.

Availability: Available for non-exclusive licensing.

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

Mucin Binding Lectin Imaging Agents for Colonic Polyp Imaging

Description of Technology: Available for licensing and commercial development is an imaging agent specific for colonic polyps that overexpress glycoprotein α-L-fucose containing mucins. Colon cancer is the second leading cause of cancer related deaths in the United States. The legume protein *Ulex* europaeus agglutinin I (UEA–1) has shown high specificity to α-L-fucose glycoproteins. Colonic mucosal neoplasia and/or polyps with high surface expression of α-L-fucosyl terminal residues can be specifically targeted with UEA–1 contrast agents. In one example, a computer tomography (CT) agent made from Iodine-127 (^{127}I) labeled UEA–1 (I–UEA–1) and encapsulated into polymeric liposome nanoparticles was used to image murine colonic polyps. Ideally, the inventors envision a contrast agent that can be administered orally (e.g., liquid or pill form) and that would eliminate a patient's need to drink harsh enema/contrast solutions prior to CT imaging.

Applications: Colon cancer; Cancer Imaging; Contrast Agents; CT colonography

Inventors: Ronald M. Summers, Jianwu Xie, Celeste Roney (CC).

Relevant Publications:

1. J Xie *et al.* Oral contrast enhanced MicroCT virtual colonoscopy of APC knockout mouse colon polyp model. Gastroenterology. 2007 Apr;132(4), Suppl. 1, Abstract No. M1063, pp A-353–A-354.

2. C Roney *et al.* Glycoprotein expression by adenomatous polyps of the colon. SPIE 2008 (in press).

3. SD O'Connor *et al.* Oral contrast adherence to polyps on CT colonography. J Comput Assist Tomogr. 2006 Jan–Feb;30(1):51–57.

Patent Status: U.S. Provisional Application filed 15 Feb 2008 (HHS Ref. No. E–254–2007/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5010; *shmilovm@mail.nih.gov*.

N–Acetyl Mannosamine as a Therapeutic Agent

Description of Technology: N–Acetyl Mannosamine is a precursor for the synthesis of sugar molecules known as sialic acids which play an important role in specific biological processes such as cellular adhesion, cellular communication and signal transduction. Lack of sialic acids also play an important role in disease processes such as cancer, inflammation and immunity.

This invention relates to methods of administering N–Acetyl Mannosamine or its derivative (to produce sialic acid in patients who are deficient in the sugar molecule) to treat muscular atrophy including hereditary inclusion body myopathy (HIBM) and distal myopathy with rimmed vacuoles (Nonaka myopathy). Certain kidney conditions such as those arising from hyposialytion of kidney membranes may be treated by this method as well.

Applications: Treatment of rare diseases such as HIBM and Nonaka myopathy.

Treatment of kidney conditions involving sialic acid deficiencies resulting in proteinuria and hematuria.

May be useful in treating other diseases involving sialic acid deficiencies.

Publication: B Galeano *et al.* Mutation in the key enzyme of sialic acid biosynthesis causes severe glomerular proteinuria and is rescued by N–acetylmannosamine. J Clin Invest. 2007 Jun;117(6):1585–1594.

Inventors: Marjan Huizing *et al.* (NHGRI).

Patent Status: U.S. Provisional Application No. 60/932,451 filed 31 May 2007 (HHS Reference No. E–217–2007/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov*.

Collaborative Research Opportunity: The National Human Genome Research Institute, Medical Genetics Branch, Cell Biology of Metabolic Disorders unit is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize N–acetylmannosamine as a therapeutic agent. Please contact Marjan Huizing at 301–402–2797or *mhuizing@mail.nih.gov* for more information.

Nitrite Adjunctive Therapy to Enhance Efficacy of Reperfusion Therapy for Acute Myocardial Infarction

Description of Technology: The treatment of coronary heart disease is a multi-billion dollar market. In the case of acute myocardial infarction (MI), more commonly known as a heart attack, the patient receives a number of

diagnostic tests to determine the type and location of the heart damage. Most patients with ST segment elevation are treated with percutaneous coronary intervention (PCI) or thrombolysis. While current therapies, that attempt to reestablish the blood flow and limit ischemia, can be effective, practical delays between symptom presentation and intervention compromise the amount of myocardial salvage. Moreover, the elapsed time prior to PCI is closely related to the clinical outcome. This has resulted in a mortality rate of 7% after MI and nearly all patients suffer from some degree of myocardial necrosis. However, the use of adjunctive pharmacological therapies can improve myocardial salvage following acute percutaneous reperfusion of an acute MI and substantially impact cardiac function.

This technology is a method of using nitrite as an adjunctive therapy to enhance efficacy of reperfusion therapy for acute MI. Evidence suggests that anion nitrite (NO_2) is a physiological signaling molecule with roles in intravascular endocrine nitric oxide (NO) transport, hypoxic vasodilation, signaling, and cytoprotection. In addition, nitrite has the characteristics of an ideal adjunctive therapy that now appears ready for translation to human clinical trials. The benefits of nitrite therapy include (1) Significant cardioprotection after prolonged ischemia, (2) simple administration, (3) low dose for pharmacological action, (4) short half-life (5) minimal side effects, (6) low expense, (7) rapid onset of action. Additionally, the therapy utilizes a cardioprotective mechanism that is not dependent on vasodilation or pressure rate changes. The use and dosing protocols of nitrite, as described by this technology, could limit MI and apoptosis in the reperfusion phase of injury and provide a remarkable degree of cardioprotection.

Applications: Treatment or amelioration of myocardial salvage following acute percutaneous reperfusion of an acute MI.

Development Status: Clinical Development.

Inventors: Mark T. Gladwin *et al.* (NHLBI).

Relevant Publications:

1. MT Gladwin, JH Shelhamer, AN Schechter, ME Pease-Fye, MA Waclawiw, JA Panza, FP Ognibene, RO Cannon 3rd. Role of circulating nitrite and S–nitrosohemoglobin in the regulation of regional blood flow in humans. Proc Natl Acad Sci U S A. 2000 Oct 10;97(21):11482–11487.

2. RO Cannon 3rd, AN Schechter, JA Panza, FP Ognibene, ME Pease-Fye, MA Waclawiw, JH Shelhamer, MT Gladwin. Effects of inhaled nitric oxide on regional blood flow are consistent with intravascular nitric oxide delivery. J Clin Invest. 2001 Jul;108(2):279–287.

Patent Status: U.S. Provisional Application No. 60/911,026 filed 10 Apr 2007 (HHS Reference No. E–023–2007/0–US–01)

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov*.

Collaborative Research Opportunity: The NHLBI Pulmonary and Vascular Medicine Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize nitrite adjunctive therapy to enhance efficacy of reperfusion therapy for acute myocardial infarction. Please contact Dr. Mark Gladwin at 301–435–2310 for more information.

Compositions and Methods for Increasing Recombinant Protein Yields Through the Modification of Cellular Properties

Description of Technology: This technology relates to compositions and methods for improving the growth characteristics of cells engineered to produce biologically active products such as antibodies or glycosylated proteins. Featured is a method that uses gene candidates (e.g., cdkl3, siat7e, or lama4), or their expressed or inhibited products in cell lines, such as Human Embryonic Kidney (including HEK–293), HeLa, or Chinese Hamster Ovary (CHO). The gene expression modulates growth characteristics, such as adhesion properties, of the cell lines thereby increasing recombinant protein yields and reducing product production costs.

Applications: This technology may be used to improve production of therapeutic and/or diagnostic compounds, including therapeutic proteins or monoclonal antibodies from mammalian cells. Optimization of mammalian cells for use as expression systems in the production of biologically active products is very difficult. For certain applications, anchorage-independent cell lines may be preferred, whereas for other applications, a cell line that adheres to a surface, e.g., is anchorage-dependent, may be preferable. This technology provides a method for identifying a gene whose expression modulates such cellular adhesion characteristics. This method thus leads to an increase in the expression or yield of polypeptides, including therapeutic biologicals, such as antibodies, cytokines, growth factors, enzymes, immunomodulators, thrombolytics, glycosylated proteins, secreted proteins, and DNA sequences encoding such polypeptides and a reduction in the associated costs of such biological products.

Advantages: This technology offers the ability to improve yields and reduce the cost associated with the production of recombinant protein products through the selection of cell lines having: Altered growth characteristics; altered adhesion characteristics; altered rate of proliferation; improvement in cell density growth; improvement in recombinant protein expression level.

Market: Biopharmaceuticals, including recombinant therapeutic proteins and monoclonal antibody-based products used for in vivo medical purposes and nucleic acid based medicinal products now represent approximately one in every four new pharmaceuticals on the market. The market size has been estimated at $33 billion in 2004 and is projected to reach $70 billion by the end of the decade. The list of approved biopharmaceuticals includes recombinant hormones and growth factors, mAB-based products and therapeutic enzymes as well as recombinant vaccines and nucleic acid based products.

Mammalian cells are widely used expression systems for the production of biopharmaceuticals. Human embryo kidney (including HEK–293) and Chinese hamster ovary (CHO) are host cell of choice. The genes identified in this technology (e.g., cdkl3, sia7e, or lama4) can be used to modify these important cell based systems.

This technology is ready for use in drug/vaccine discovery, production and development. The technology provides methods for identification of specific gene targets useful for altering the production properties of either existing cell lines to improve yields or with new cell lines for the production of therapeutic and or diagnostic compounds from mammalian cells.

Companies that are actively seeking production platforms based on mammalian cell lines that offer high efficiency, high throughput systems for protein production or analysis at lower cost and ease of scale-up would be potential licensors of this technology.

Development Status: Late Stage—Ready for Production.

Inventors: Joseph Shiloach (NIDDK), Pratik Jaluria (NIDDK).

Related Publication: P Jaluria *et al.* Application of microarrays to identify and characterize genes involved in attachment dependence in HeLa cells. Metab Eng. 2007 May;9(3):241–251.

Patent Status: U.S. Provisional Application No. 60/840,381 filed 24 Aug 2006 (HHS Reference No. E–149–2006/0–US–01); PCT Application No. PCT/US2007/018699 filed 24 Aug 2007 (HHS Reference No. E–149–2006/0–PCT–02).

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

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

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases, Biotechnology Core Laboratory, is seeking parties interested in collaborative research projects directed toward the use of this technology with cells for drug and vaccine production and development, including growth optimization, production and product recovery processes. For more information, please contact Dr. Joseph Shiloach, *josephs@intra.niddk.nih.gov*, or Rochelle S. Blaustein at *Rochelle.Blaustein@nih.gov*.

March 20, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–6316 Filed 3–27–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 purpose of this meeting is to evaluate proposals for support through the RAID program by making available to the research community, on a competitive basis, NCI new agent development contract resources for the preclinical development of drugs and biologics. The outcome of the evaluation will be a decision whether NCI should support the request and make available contract resources for support through the RAID program to the research community and NCI new agent development for the preclinical development of drugs and biologics. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Rapid Access to Intervention Development.

Date: May 2, 2008.

Time: 8:30 a.m.–5 p.m.

Agenda: To evaluate the Rapid Access to Intervention Development Portfolio.

Place: National Institutes of Health, Executive Plaza North, Conference Room G, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Phyllis G. Bryant, Executive Secretary, Program Analyst, Developmental Therapeutics Program, National Cancer Institute, NIH, 6130 Executive Boulevard, Rm. 8022, Bethesda, MD 20892, (301) 496–8720.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 20, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6198 Filed 3–27–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; NHLBI Institutional Training Mechanism Review Committee.

Date: June 19–20, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Charles Joyce, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892–7924, 301–435–0288, *cjoyce@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 20, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6196 Filed 3–27–08; 8:45 am]

BILLING CODE 4140–01–M

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. 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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 To Review Contract Proposals.

Date: April 16–17, 2008.

Time: 7:30 a.m. to 7 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hilton Washington DC/Silver Spring; 8727 Colesville Road, Silver Spring, MD 20910.