1. *Type of Information Collection Request:* Extension of currently approved collection.

Title of Information Collection: Hospice Cost Report and Supporting Regulations Contained in 42 CFR 413.20 and 413.24.

Use: The hospice cost report is the mechanism used to collect data from providers for rate evaluations for the Prospective Payment System (PPS). Once CMS obtains this information, we will update the PPS as mandated by Congress.

Form Number: CMS–R–249 (OMB#: 0938–0758).

Frequency: Annually.

Affected Public: Not-for-profit Institutions and Business or other for-profit.

Number of Respondents: 1,720.

Total Annual Responses: 1,720.

Total Annual Hours: 302,720.

2. *Type of Information Collection Request:* Extension of currently approved collection.

Title of Information Collection: Outpatient Rehabilitation Cost Report and Supporting Regulations Contained in 42 CFR 413.20 and 413.24.

Use: This form is used by community mental health centers to report their health care costs to determine the amount of reimbursement for services furnished to Medicare beneficiaries.

Form Number: CMS–2088–92 (OMB#: 0938–0037).

Frequency: Annually.

Affected Public: Business or other for-profit; Not-for profit Institutions, State, Local or Tribal governments.

Number of Respondents: 618.

Total Annual Responses: 618.

Total Annual Hours: 61,800.

3. *Type of Information Collection Request:* Extension of a currently approved collection.

Title of Information Collection: Hospital Conditions of Participation (COP) and Supporting Regulations in 42 CFR 482.12, 482.13, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.45, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62, 485.618 and 485.631.

Use: Hospitals seeking to participate in the Medicare and Medicaid programs must meet the Conditions of Participation (COP) for Hospitals, 42 CFR Part 482. The information collection requirements contained in this package are needed to implement the Medicare and Medicaid COP for hospitals and critical access hospitals (CAHs).

Form Number: CMS–R–48 (OMB# 0938–0328).

Frequency: Annually.

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

Number of Respondents: 6,085.

Total Annual Responses: 6,085.

Total Annual Hours: 5,511,544.

4. *Type of Information Collection Request:* Revision of currently approved collection.

Title of Information Collection: ESRD Beneficiary Selection and Supporting Regulations Contained in 42 CFR 414.330.

Use: ESRD facilities have each new home dialysis patient select one of two methods to handle Medicare reimbursement. The intermediaries pay for the beneficiaries selecting Method I and the carriers pay for the beneficiaries selecting Method II. This system was developed to avoid duplicate billing by both intermediaries and carriers.

Form Number: CMS–382 (OMB#: 0938–0372).

Frequency: Other: One time only.

Affected Public: Individuals or Households, Business or other for-profit, and Not-for profit Institutions.

Number of Respondents: 7,400.

Total Annual Responses: 7,400.

Total Annual Hours: 617.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/regulations/pra/,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 18, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–26286 Filed 12–2–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0114]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 22, 2004, (69 FR 43852) the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0130. The approval expires on November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 26, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26581 Filed 12–2–04; 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, DHHS.

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.

Adoptive Immunotherapy With Enhanced T–Lymphocyte Survival

Richard Morgan (NCI) and Steven Rosenberg (NCI)

U.S. Provisional Patent Application No. 60/617,340 filed 08 Oct 2004 (DHHS Reference No E–340–2004/0–US–01) and U.S. Provisional Patent Application filed 12 Oct 2004 (DHHS Reference No E–340–2004/1–US–01)

Licensing Contact: Jeff Walenta; (301) 435–4633; *walentaj@mail.nih.gov.*

Adoptive immunotherapy strategies have existed for several years now and many have proven to be highly successful in a limited subset of patients. This limited response rate among a diverse patient population may not be surprising, given the complexity of the immune system and the complicated evolution of a normal cell to a immune evading malignancy. A common observation amongst most patients that did not respond to adoptive therapy strategies is that the immune response to the cancer was not sustained.

A number of cytokines have been shown to sustain a T-cell response when administered systemically with autologous isolated T-cells. However, the systemic delivery of many cytokines, such as IL–2, will cause significant toxicity before the beneficial immunologic effects of the autologous T-cells can occur. This invention describes a method of transfecting isolated autologous T-Lymphocytes with endogenous cytokines, for example IL–7 and IL–15, to sustain an adoptive T-lymphocyte response without systemic toxicity. The invention also describes a method for improving expression of transfected cytokines via a codon optimized IL–15 vector.

This invention was developed at the NCI Surgery Branch. The Surgery Branch plans to initiate clinical studies utilizing this technology and collaborative opportunities may be available. Publications which may provide background information for this technology include:

1. Rosenberg, SA and Dudley, ME. Cancer regression in patients with metastatic melanoma after the transfer of autologous antitumor lymphocytes. Proc Natl Acad Sci U S A. 2004 Oct 5;101 Suppl 2:14639–45. Epub 2004 Sep 20.

2. Klebanoff CA, Finkelstein SE, Surman DR, Lichtman MK, Gattinoni L, Theoret MR, Grewal N, Spiess PJ, Antony PA, Palmer DC, Tagaya Y, Rosenberg SA, Waldmann TA, Restifo NP. IL–15 enhances the in vivo antitumor activity of tumor-reactive CD8+ T cells. Proc Natl Acad Sci U S A. 2004 Feb 17;101(7):1969–74. Epub 2004 Feb 04.

3. Dudley ME, Rosenberg SA. Adoptive-cell-transfer therapy for the treatment of patients with cancer. Nat Rev Cancer. 2003 Sep;3(9):666–75. Review.

4. Liu K, Rosenberg SA. Interleukin-2-independent proliferation of human melanoma-reactive T lymphocytes transduced with an exogenous IL–2 gene is stimulation dependent. J Immunother. 2003 May–Jun;26(3):190–201.

5. Liu K, Rosenberg SA. Transduction of an IL–2 gene into human melanoma-reactive lymphocytes results in their continued growth in the absence of exogenous IL–2 and maintenance of specific antitumor activity. J Immunol. 2001 Dec 1;167(11):6356–65.

A New Approach Toward Macrocyclization of Peptides

Terrence R. Burke, Jr. *et al.* (NCI)

DHHS Reference No. E–327–2004/0–US–01

Licensing Contact: George Pipia; (301) 435–5560; *pipiag@mail.nih.gov*

The invention relates to cyclic peptides for use as inhibitors of oncogenic signal transduction for cancer therapy. The current invention discloses novel cyclic peptides resulting from ring closure between the alpha and beta positions of C-terminal and N-terminal residues, respectively. This allows retention of key functionality needed for binding to target proteins, which results in increased affinity.

Cyclic peptides that retain key chemical functionality may be of particular importance in inhibiting oncogenic signaling cascades for therapeutic benefit. In many oncogenic signal transduction cascades, tyrosine protein kinases phosphorylated target proteins. Propagation of the signal is achieved when these phosphorylated tyrosyl residues are bound by proteins bearing SH2 domains. Cyclic peptides that disrupt the interaction between proteins with SH2 domains and proteins with phosphorylated tyrosyl residues could block oncogenic signals and serve as powerful cancer therapeutic agents. As several moieties are required for optimal recognition by SH2 domains, the cyclic peptides of the current invention could be more effective inhibitors of SH2 domain proteins, or of other proteins where increased specificity is desired. The inventors have determined that the peptides of the current invention bind to the Grb2–SH2 domain with high affinity, supporting their potential use as therapeutic agents. The current invention is related to U.S. Provisional Application No. 60/504,241; DHHS Reference No. E–315–2003/0–US–01.

cDNA for Murine PEDF

IR Rodriguez, GJ Chader, VK Singh (NEI)

DHHS Reference No. E–112–2004/0—Research Tool

Licensing Contact: Susan Rucker; (301) 435–4478; *ruckersu@mail.nih.gov.*

This technology is a cDNA, obtained from mouse liver, which encodes the open reading frame of the murine homolog of pigment epithelium-derived factor (mPEDF). PEDF is a serpin protein that has not been demonstrated to have serine protease activity in a physiological setting but which exhibits diverse biologic properties including neurotrophic activity and anti-angiogenic activity. The mPEDF cDNA may be used to study PEDF function and may be particularly useful in research applications comparing mPEDF to hPEDF. The cDNA, provided as a plasmid designated pMOU12A, can be readily inserted into an expression vector. The cDNA is further described in Singh, VK *et al.* Mol Vision 4: 7 (April 20, 1998). No patent application has been or will be filed by the NIH for this technology. The cDNA is available through a biological materials license agreement.

Novel Compounds That Release Both Nitric Oxide (NO) and Nitroxyl (HNO) as Pharmacological Agents

Larry Keefer *et al.* (NCI)

U.S. Provisional Application No. 60/540,368 filed 30 Jan 2004 (DHHS Reference No. E–095–2004/0–US–01)

Licensing Contact: Norbert Pontzer; (301) 435–5502; *pontzern@mail.nih.gov*

The simple diatomic molecule nitric oxide (NO) is known to play a diverse and complex role in cellular physiology. NCI scientists have previously produced a number of nucleophile/nitric oxide adducts (diazeniumdiolates) that spontaneously dissociate at physiological pH to release nitric oxide by stable first order kinetics. These compounds are finding diverse therapeutic uses as pharmacological agents. Growing evidence suggests that redox related forms of NO such as nitroxyl (HNO) also have a rich pharmacological potential and may complement that of NO. The present invention provides compounds that release both NO and HNO under physiological conditions, compositions comprising those compounds and methods of using the compounds alone and in conjunction with medical devices such as stents to treat disease. Included among the compositions claimed is a glycosylated prodrug derivative that can be cleaved to active form by β–D-glucosidase (J. Am. Chem. Soc. 2004, 126, 12880–12887).

A Method With Increased Yield for Production of Polysaccharide-Protein Conjugate Vaccines Using Hydrazide Chemistry

Che-Hung Robert Lee and Carl Frasch (FDA), U.S. Provisional Application No. 60/493,389 filed 06 Aug 2003 (DHHS Reference No. E–301–2003/0–US–01)

Licensing Contact: Peter Soukas; (301) 435–4646; *soukasp@mail.nih.gov.*

Current methods for synthesis and manufacturing of polysaccharide-protein conjugate vaccines employ conjugation reactions with low efficiency (about twenty percent). This means that up to eighty percent of the added activated polysaccharide (PS) is lost. In addition, inclusion of a chromatographic process for purification of the conjugates from unconjugated PS is required.

The present invention utilizes the characteristic chemical property of hydrazide groups on one reactant to react with aldehyde groups or cyanate esters on the other reactant with an improved conjugate yield of at least sixty percent. With this conjugation efficiency the leftover unconjugated protein and polysaccharide would not need to be removed and thus the purification process of the conjugate product can be limited to diafiltration to remove the by-products of small molecules. The new conjugation reaction can be carried out within one or two days with reactant concentrations between 1 and 25 mg/mL at PS/protein ratios from 1:2 to 3:1, at temperatures between 4 and 40 degrees Centigrade, and in a pH range of 5.5 to 7.4, optimal conditions varying from PS to PS.

Therefore, this invention can reduce the cost of conjugate vaccine manufacture.

Dated: November 24, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–26596 Filed 12–2–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Dendrimer Based MRI Contrast Agents

AGENCY: National Institutes of Health, Public Health Service, DHHS

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive worldwide license to practice the invention embodied in:

E–151–2002 ''Methods for Functional Kidney Imaging Using Dendrimer Conjugate Agents,'' U.S. Patent App. Serial No. 10/229,316 and International Patent Application No. PCT/US02/27297;

E–240–2001 ''Macromolecular Imaging Agents for Liver Imaging,'' U.S. Patent App. Serial No. 10/481,706, International Patent Application No. PCT/US02/20118, European Patent Application 02752092.3;

E–338–2003 ''Method for Imaging the Lymphatic Systems Using Dendrimer-Based Contrast Agents,'' U.S. Patent App. Serial No. 10/756,948;

E–317–2004 ''Synthetic Metal Ion Chelating Amino Acid Suitable for Use in Solid Phase Peptide Synthesis.'' Filed October 4, 2004 (Serial Number to be determined);

to Dendritic NanoTechnologies, Inc., a Delaware corporation having its principle place of business in Mount Pleasant, Michigan. The United States of America is the assignee to the patent rights of the above inventions.

The contemplated exclusive license may be granted in the field of use of MRI imaging contrast agents.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before February 1, 2005 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael A. Shmilovich, Esq., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5019; Facsimile: (301) 402–0220; E-mail: *shmilovm@mail.nih.gov.* A signed confidentiality nondisclosure agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The patent applications intended for licensure disclose and/or cover the following:

E–151–2002—Methods for Functional Kidney Imaging Using Dendrimer Conjugate Agents

The invention is a method for functional kidney imaging using small dendrimer-based MRI contrast agents that transiently accumulate in renal tubules. The accumulation enables visualization of renal structure and function, permitting assessment of structural and functional damage to the kidneys. Six small dendrimer-based MRI contrast agents have been synthesized, and their pharmacokinetics, whole body retention and renal MRI images were evaluated in mice. Surprisingly, despite having unequal renal clearance properties, all of the dendrimer agents clearly visualized the renal anatomy and proximal straight tubules of the mice better than Gd-[DTPA]-dimeglumine. Dendrimer conjugate contrast agents prepared from PAMAM–G2D, DAB–G3D and DAB–G2D dendrimers were excreted rapidly and may be acceptable for use in clinical applications.

E–240–2001—Macromolecular Imaging Agents for Liver Imaging

The invention is a macromolecular imaging agent comprising a polyalkylenimine dendrimer conjugated to a metal chelate that has been shown to be an excellent agent for imaging liver micrometastases as small as about 0.3 mm in a magnetic resonance image of the human liver. In a particular embodiment, the imaging agent is a diaminobutane-core polypropylenimine dendrimer having surface amino groups conjugated to gadolinium metal chelates. The invention makes possible the earlier detection of metastatic disease, leading to earlier application of a therapeutic regime and an improved prognosis. Accordingly, the method of