DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10101, CMS–10093, CMS–304&304a, CMS–565, and CMS–R–246]

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

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Survey of Medicare Preferred Provider Organization Demonstration *Form No.:* CMS–10101 (OMB# 0938–NEW); *Use:* This information collection will be used to collect information from Medicare Beneficiaries to understand beneficiary experiences with the new managed care option and to understand which Medicare beneficiaries are attracted to the PPO model and why. CMS also wants to know what both enrollees and non-enrollees in PPOs know and understand about this new option; *Frequency:* Other: One-time Only; *Affected Public:* Individuals or Households; *Number of Respondents:* 38,216; *Total Annual Responses:* 38,216; *Total Annual Hours:* 9,556.

2. *Type of Information Request:* Extension of a currently approved collection; *Type of Information Collection:* CMS/AoA Aging and Disability Resource Center Grant Program; *CMS Form Number:* CMS–10093 (OMB# 0938–0903); *Use:* Information sought by CMSO/DEHPG is needed to award competitive grants to States to develop Aging and Disability Resource Centers; *Frequency:* Semi-annually; *Affected Public:* State, local, or tribal government, Not-for-profit institutions, Business or other for-profit; *Number of Respondents:* 24; *Total Annual Responses:* 48; *Total Annual Burden Hours:* 960.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate; *Form No.:* CMS–304 and CMS–304a (OMB 0938–0676); *Use:* Section 1927 of the Social Security Act requires State Medicaid agencies to report to drug manufacturers and CMS on the drug utilization for their State and the amount of rebate to be paid by the manufacturer; *Frequency:* Quarterly; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 6,125.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Qualification Statement for Federal Employees and Supporting Regulations in 42 CFR 406.15; *Form No.:* CMS–565 (OMB# 0938–0501); *Use:* The CMS–565 is completed by individuals filing for hospital insurance ([HI] Part A) benefits based upon their federal employment. This information is needed to determine if SSA/CMS can use (deem) federal employment prior to 1983 to provide quarters of coverage so the individual can qualify for free hospital insurance; *Frequency:* Other: One-time-only; *Affected Public:* Individuals or Households, Federal Government, State, Local, or Tribal Government; *Number of Respondents:* 4,300; *Total Annual Responses:* 4,300; *Total Annual Hours:* 717.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Consumer Assessment of Health Plan Survey—Medicare + Choice (CAHPS–M+C); *Form No.:* CMS–R–246(OMB# 0938–0732); *Use:* Under the Balanced Budget Act of 1997, CMS is required to provide general and plan comparative information to beneficiaries that will help them make more informed health plan choices. A CAHPS fee-for-service survey is needed to provide information comparable to those data collected from the CAHPS managed care survey; *Frequency:* Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 168,000; *Total Annual Responses:* 168,000; *Total Annual Hours:* 55,450.

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://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.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: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 22, 2004.

Melissa Musotto,

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

[FR Doc. 04–1984 Filed 1–29–04; 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, 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.

Analogs of Thalidomide as Potential Angiogenesis Inhibitors

William D. Figg, Erin Lepper (NCI)
U.S. Provisional Application No. 60/486,515 filed 11 Jul 2003 (DHHS Reference No. E–272–2003/0–US–01)
Licensing Contact: Matthew Kiser; 301/435–5236; *kiserm@mail.nih.gov.*

The present disclosure relates to anti-angiogenesis compositions and methods, and particularly thalidomide analogs that actively inhibit angiogenesis in humans and animals.

Angiogenesis is the formation of new blood vessels from pre-existing vessels. Angiogenesis is prominent in solid tumor formation and metastasis. A tumor requires formation of a network of blood vessels to sustain the nutrient and oxygen supply for continued growth. Some tumors in which angiogenesis is important include most solid tumors and benign tumors, such as acoustic neuroma, neurofibroma, trachoma, and pyogenic granulomas. Prevention of angiogenesis could halt the growth of these tumors and the resultant damage due to the presence of the tumor.

The subject application discloses active thalidomide analogs that exhibit enhanced potency in the inhibition of undesirable angiogenesis, and methods for using these compounds to treat angiogenesis and solid tumors. In particular, the presently disclosed method provides for inhibiting unwanted angiogenesis in a human or animal by administering to the human or animal with the undesired angiogenesis a composition comprising an effective amount of the active thalidomide analogs. According to a more specific aspect, the method involves inhibiting angiogenesis by exposing a mass having the undesirable angiogenesis to an angiogenesis inhibiting amount of one or more compounds, or pharmaceutically acceptable salts of such compounds.

Serine Protease Inhibitors

Peter P. Roller, Peng Li (NCI)
U.S. Provisional Application No. 60/507,583 filed 30 Sep 2003 (DHHS Reference No. E–272–2002/0–US–01)
Licensing Contact: Matthew Kiser; 301/435–5236; *kiserm@mail.nih.gov.*

This disclosure concerns novel serine protease inhibitors and methods for using the inhibitors to reduce tumor progression and/or metastasis. Embodiments of the inhibitors are highly effective, selective inhibitors of matriptase, which has been implicated in tissue remodeling associated with the growth of cancerous tumors and cancer metastasis.

Angiogenesis and tumor invasion require that the normal tissue surrounding the tumor be broken down in a process referred to as tissue remodeling. Tissue remodeling is accomplished by a host of enzymes that break down the proteins in the normal tissue barriers comprising the extracellular matrix. Among the enzymes associated with degradation of the extracellular matrix and tissue remodeling are a number of proteases. The expression of some of these proteases has been correlated with tumor progression.

The disclosed compounds can be used to inhibit matriptase, MTSP1, or both, *in vitro* and *in vivo* and thus can be used in the prevention or treatment of conditions characterized by abnormal or pathological serine protease activity. For example, the compounds are useful for prevention or treatment of conditions characterized by the pathological degradation of the extracellular matrix, such as conditions characterized by neovascularization or angiogenesis, including cancerous conditions, particularly metastatic cancerous conditions where matriptase is implicated. The disclosed compounds can be used to decrease the degradation of the cellular matrix and thereby reduce concomitant tumor progression and metastasis. Conditions characterized by abnormal or pathological serine protease activity that can be treated according to the disclosed method include those characterized by abnormal cell growth and/or differentiation, such as cancers and other neoplastic conditions. Typical examples of cancers that may be treated according to the disclosed inhibitors and method include colon, pancreatic, prostate, head and neck, gastric, renal, and brain cancers.

Methods for Inhibiting Chaperone Proteins

Monica Marcu, Leonard Neckers, Theodor Schulte (NCI)
U.S. Patent Application No. 09/936,449 filed 20 Dec 2001 (DHHS Reference No. E–084–1999/0–US–07), with priority to 12 Mar 1999
Licensing Contact: George Pipia; 301/435–5560; *pipiag@mail.nih.gov.*

This invention is directed to depletion of the Heat Shock Protein (HSP)–90 with novobiocin. Hsp90 is an essential and abundant chaperone in eukaryotes. It is considered today an exciting molecular target for cancer therapy. NIH inventors demonstrated previously that the gyrase-B inhibitor, novobiocin, and its related coumarin derivatives interact with Hsp90, causing *in vitro* and *in vivo* depletion of key regulatory Hsp90-dependent proteins. Using deletion/mutation analysis, the inventors have identified the novobiocin binding domain on Hsp90 and demonstrated that it overlaps a functional ATP binding site, which was previously unknown. These results identify a second site on Hsp90 where the binding of small molecule inhibitors can significantly impact this chaperone's function, and thus support the hypothesis that both N- and C-terminal domains of Hsp90 interact to modulate chaperone activity. The inventors have performed preliminary *in vivo* experiments, treating mice carrying tumor xenografts with novobiocin encapsulated in Alzet pumps (slow, constant release for one month). The treated mice exhibited significantly slower tumor growth. Results of these studies demonstrated a significantly slower growth of tumors.

Dated: January 23, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–1994 Filed 1–29–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; Chairpersons, Boards of Scientific Counselors for Institutes and Centers at the National Institutes of Health

Notice is hereby given of a meeting scheduled by the Deputy Director for Intramural Research at the National Institutes of Health (NIH) with the Chairpersons of the Boards of Scientific Counselors. The Boards of Scientific Counselors are an advisory group to the Scientific Directors of the Intramural Research Programs at the NIH. This meeting will take place on February 6, 2004 from 9 a.m. to 3 p.m., at the NIH, 9000 Rockville Pike, Bethesda, MD, Building 1, Wilson Hall. The meeting will include a discussion of policies and procedures that apply to the regular review of NIH intramural scientists and their work, with special emphasis on clinical research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Colleen Crone at the Office of Intramural Research, NIH, Building 1, Room 103, Telephone (301) 496–1921 or