

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Hospice Request for Certification in the Medicare Program; *Form No.:* HCFA-417 (OMB# 0938-0313); *Use:* The Hospice Request for Certification Form is used for hospice identification, screening, and to initiate the certification process. The information captured on this form is entered into a data base which assists HCFA in determining whether providers have sufficient personnel to participate in the Medicare program; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 2,286; *Total Annual Responses:* 2,286; *Total Annual Hours:* 572.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA 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: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 22, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1060-N3]

RIN 0938-AJ57

Medicare Program; Cost-of-Living Adjustment (COLA) for the Territory of Guam in the Schedules of Per-Visit Limitations on Home Health Agency Costs

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the cost-of-living adjustment for the territory of Guam for the schedules of per-visit limitations on home health agency (HHA) costs for open cost reporting periods beginning on or after October 1, 1997 and portions of cost reporting periods beginning before October 1, 2000.

EFFECTIVE DATE: This notice is effective on August 6, 2001.

FOR FURTHER INFORMATION CONTACT: Michael D. Bussacca, (410) 786-4602.

SUPPLEMENTARY INFORMATION: We have published the following notices to announce the HHA interim payment system per-visit limitations and updates to those limitations. These notices were published on January 2, 1998 (63 FR 89), effective on October 1, 1997; August 1, 1998 (63 FR 42911), effective October 1, 1998; and August 5, 1999 (64 FR 42766), effective on October 1, 1999.

It was our intention to include a COLA for each U.S. State and Territory eligible for those adjustments under the Office of Personnel Management (OPM) regulations. We inadvertently published these notices without a COLA for the Territory of Guam because we did not include COLA factors for Guam in the per-visit tables in the applicable notices. The COLA factor for Guam should have been 1.225 in each of these notices. The OPM has not updated the factor for Guam for these 3 cost reporting years; therefore, the COLA remains 1.225 for each cost reporting period. The COLA factor applies to the per-visit limitations for all open cost reporting periods beginning on or after October 1, 1997 (COLA Table at 63 FR 96), October 1, 1998 (COLA Table at 63 FR 42926), and October 1, 1999 (COLA Table at 64 FR 42777).

Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the

Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). We have determined that this is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. For purposes of the RFA, most HHAs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. We believe that there are no costs associated with this notice that apply to these governmental and private sectors. Therefore, the law does not apply.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of States.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that

this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

This notice is not a major rule as defined in title 5, United States Code, section 804(2).

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Authority: Section of the Social Security Act (42 U.S.C.) (Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: February 16, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: March 14, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01-16865 Filed 7-3-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunity for License(s) and/or Cooperative Research and Development Agreement(s) (CRADAs) for the Development of Geldanamycin Analogs for Clinical Use

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks Licensee(s) and/or Cooperative Research and Development Agreement (CRADA) Collaborator(s) for the development of geldanamycin analogs for clinical use in three areas. The three areas are: (1) A unique clinical formulation of 17-allylaminogeldanamycin (17-AAG). (2) A suite of geldanamycin analogs (other than 17-AAG) modified at the 11 and/or 17 positions, several of which have improved solubility and reduced toxicity in comparison to geldanamycin. (3) A coupled met kinase-uPA kinase assay, as described in Cancer Research 60 (2): 342-9, and data and expertise regarding geldanamycin analog activity as measured by that assay. The invention for item (1) is claimed in PCT Patent Application PCT/US99/30631 entitled "Water-Insoluble Drug Delivery System"; the inventions for item (2) are claimed in U.S. Patent Application 60/

246,258, entitled "Geldanamycin Derivatives Having Selective Affinity for HSP-90 and Methods of Using Same," U.S. Patent Application 60/280,016, entitled "Geldanamycin Derivatives Having Selective Affinity for HSP90 over GRP94 and Method of Using Same," and U.S. Patent Application 60/280,078, entitled "Geldanamycin Derivatives and Method of Treating Cancer Using Same"; the technology for item (3) is described in Cancer Research 60 (2): 342-9, "The Geldanamycins Are Potent Inhibitors of the Hepatocyte Growth Factor/Scatter Factor-Met-Urokinase Plasminogen Activator-Plasmin Proteolytic Network."

DATES: Respondees interested in licensing the invention(s) will be required to submit an "Application for License to Public Health Service Inventions" no later than sixty (60) days from the date of this announcement. Applications submitted thereafter may be considered if a suitable Licensee is not selected from among the timely responses.

Interested CRADA applicants must submit to the NCI Technology Transfer Branch (TTB) a confidential proposal summary no later than sixty (60) days from the date of this announcement for consideration. CRADA proposal summaries submitted thereafter may be considered if a suitable CRADA Collaborator is not selected from among the timely responses. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

ADDRESSES: Inquiries directed to obtaining license(s) for the technology should be addressed to Kai Chen, Ph.D., M.B.A., Supervisory Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, (Tel. 301-496-7056, extension 247; FAX 301-402-0220).

CRADA inquiries and proposals regarding this opportunity should be addressed to Robert Wagner, M.S., M. Phil., Technology Transfer Specialist (Tel. 301-496-0477, FAX 301-402-2117), Technology Transfer Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: Respondees interested in licensing the technology will be required to submit an Application for License to Public Health Service Inventions. Inventions described in the patent applications are available for either exclusive or non-

exclusive licensing in accordance with 35 U.S.C. 207 and 37 CFR Part 404. Information about patent application(s) and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement.

A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into with NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987, as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and it is not a contract for the procurement of goods/services. The NCI is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NCI can contribute facilities, staff, materials, and expertise. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA. CRADA applicants should be aware that a license to the above mentioned patent rights may be necessary in order to commercialize products arising from a CRADA. The expected duration of the CRADA(s) would be for up to five (5) years. The goals of CRADAs include the rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research.

The NCI Seeks Licensee(s) and/or CRADA Collaborator(s) in One or More of the Following Areas for the Development of Geldanamycin Analogs for Clinical Use

1. *Clinical Development of 17-AAG:* Patent protection for the formulation of 17-allylaminogeldanamycin (17-AAG) for clinical use is pending. NCI is actively engaged in the clinical development of this agent and is seeking a CRADA collaborator whose role would include production of the drug for clinical trials. CRADA applicants should be aware that a license to the related patent rights may be necessary in order to commercialize products arising from the CRADA. 17-AAG is currently in Phase 1 clinical trials under an NCI-sponsored Investigational New Drug Application (IND). The data contained in this IND, along with the data that will emerge from NCI's ongoing clinical trials, would be available to the CRADA Collaborator.

2. *Optimization of Compounds for Cytotoxic Endpoints:* A suite of geldanamycin analogs (other than 17-