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]

BILLING CODE 4120–01–P

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–

AAG) modified at the 11 and/or 17 positions, several of which have improved solubility and altered toxicity in comparison to geldanamycin, are described in several pending NCI patent applications. NCI is seeking a licensee(s) and/or CRADA Collaborator(s) interested in continued optimization of compound pharmacology for selection of a compound to enter the clinic. Criteria for selection of a compound would include cytotoxic endpoints and regression of model tumors. Such a resulting compound(s) would be expected to have a different spectrum of activity or formulation as that for 17–AAG as described in (1) above.

3. *Optimization of Compounds for Anti-Metastatic Endpoint:* The technology for the coupled met kinase—uPA Kinase assay is described in Cancer Research 60 (2): 342–9. NCI research has defined this assay as generating lead compounds for anti-metastatic use. While encompassing some compounds from (2) above, lead compounds will have a very distinct set of development endpoints demonstrating suitability for long term chronic oral dosing, and will show evidence of activity in anti-metastasis and/or anti-angiogenesis assays without necessarily having evidence of activity in classical cytotoxic models. NCI is seeking a CRADA Collaborator(s) interested in using this assay to optimize compounds related to geldanamycin for use as anti-metastatic agents.

Party Contributions to CRADAS

The Role of the NCI in Each of the CRADAs May Include, but Not Be Limited to

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the CRADA Collaborator with information and data relating to the CRADA technology.
3. Planning research studies and interpreting research results.
4. Carrying out research pursuant to the planned collaboration, including, but not limited to:

(a). Screening, pharmacology and in vivo model studies for compounds pertinent to cytotoxic endpoints;

(b). Assays to optimize compounds with desired pharmacology for chronic use;

(c). Pharmacology and determination of in vivo activity of anti-metastatic compounds;

(d). Production of precursors and prodrugs from fermentation sources; and

(e). Possible sponsorship of clinical trials of promising compounds.

5. Publishing research results.

The Role of the CRADA Collaborator May Include, but Not Be Limited to

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project, including, but not limited to:

(a). Structure-based design of geldanamycin analogs with suitable properties;

(b). Chemical modification of fermented lead structures;

(c). Pharmacology, toxicology, and formulation;

(d). Support for clinical trials in the form of drug and funding.

2. Planning research studies and interpreting research results.
3. Providing technical and/or financial support to facilitate scientific goals and to further design applications of the technology outlined in the agreement.
4. Publishing research results.

Selection Criteria for Choosing the CRADA Collaborator May Include, but Not Be Limited to

1. A demonstrated background and expertise in the preclinical and clinical development of antineoplastic agents, structure-based design, and the conduct of in vivo animal model studies pertaining to metastasis or tumor regression.
2. A demonstrated record of success in pre-clinical lead selection and optimization and/or successful clinical trials of antineoplastic therapeutics leading to a commercial product.
3. The demonstration of the necessary resources to produce sufficient drug for all clinical trials in a timely manner.
4. The ability to collaborate with NCI on further research and development of the technology. This ability will be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
5. The demonstration of adequate resources to perform the research and development of the technology (e.g. facilities, personnel and expertise) and to accomplish the objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
6. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.
7. The demonstration of expertise in the commercial development and production of products related to this area of technology.
8. The ability to provide financial support for CRADA-related Government activities.
9. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
10. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.
11. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These legal provisions govern the distribution of future patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: June 25, 2001.

Kathleen Sybert,

Chief, Technology Transfer Branch, National Cancer Institute, National Institutes of Health.

Dated: June 27, 2001.

Jack Spiegel,

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

[FR Doc. 01–16762 Filed 7–3–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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 meetings.

The meetings 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.