

1986 and amendments (including 104 P.L. 133) and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Government is seeking one or more companies which, in accordance with the requirements of the regulations governing the transfer of agents in which the Government has taken an active role in developing (37 CFR 404.8), can further develop the identified compounds and related diagnostic methods through Federal Food and Drug Administration approval and to a commercially available status to meet the needs of the public and with the best terms for the Government. The government has applied for domestic and foreign patent applications directed to Fusion Proteins That Include Antibody and Non-Antibody Portions.

The Fusion Proteins comprise an IgG sequence covalently joined at the IgG hinge and Fc domain to a non-antibody effector domain such as a ligand, toxin, or receptor. The effector domain or IgG non-antibody portion may be linked to a heterologous signal peptide to facilitate secretion. The resulting fusion protein exhibits the effector properties of both the antibody and non-antibody portions. Applications of this technology include development of diagnostic methods to monitor binding and expression of a protein of interest *in vitro*, *in vivo* and *in situ* (i.e. immunohistochemistry). In addition, the technology can be used to identify agonists and antagonists that modulate the binding of an effector molecule to its target. Fusion proteins may also be employed as a therapeutic to deliver radiation, a cytotoxic agent or a drug directly to a target cell.

The LCMB, Division of Basic Sciences, NCI is interested in establishing a CRADA with one or more companies to assist in the development of diagnostic, screening and therapeutic applications of the technology. The Government will provide all available expertise and information to date and will jointly pursue pre-clinical and clinical studies as required, giving the company full access to existing data and data developed pursuant to the CRADA. The successful company will provide the necessary scientific, financial and organizational support to establish clinical efficacy and possible commercial status of subject compounds and/or diagnostic and therapeutic applications.

The expected duration of the CRADA will be two (2) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. Construction of fusion proteins comprising a molecule of interest covalently joined to an IgG hinge and Fc antibody regions.
2. Expression and harvesting of the resulting fusion protein from conditioned medium of a suitable transfectant such as NIH 3T3 cells.
3. Develop a screen of ligand-HFc on receptor or receptor-HFc on ligand to identify putative agonists and antagonists.
4. Conduct *in vitro* studies to identify putative agonists and/or antagonists by screening libraries of compounds.
5. Conduct *in vitro* and *in vivo* studies to characterize the properties of putative agonists and/or antagonists.
6. Evaluation of test results.
7. Preparation of manuscripts for publication.

Relevant Government intellectual property rights are available for licensing through the Office of Technology Transfer, National Institutes of Health.

FOR FURTHER INFORMATION CONTACT
Susan Rucker, J.D., NIH Office of Technology Transfer, 6011 Executive Blvd, Suite 325, Rockville, MD 20852, Phone: (301) 496-7056 (ext. 245); Facsimile: (301) 402-0220.

The role of the collaborator company, includes the following

For agonist/antagonist screening:

1. Provide growth factor or receptor cDNA clones for fusion protein construction if not available in NCI/LCMB clone bank
2. Scale-up production of fusion proteins constructed by NCI if required
3. Conduct *in vitro* studies to identify putative antagonists/agonists by screening libraries of compounds
4. Conduct *in vitro* and *in vivo* studies to characterize the properties of putative antagonists/agonists
5. Conduct clinical studies of best candidates

For ligand-mediated histochemical experiments:

1. Test conditioned medium for suitability in histochemical experiments
2. Screen tumor samples or biopsies for reactivity
3. Conduct clinical studies of diagnostic test

Criteria for choosing the company include its demonstrated experience and commitment to the following:

1. Scientific expertise in and demonstrated commitment to the treatment of neoplasia, arteriosclerosis, fibrotic diseases and related disorders.
2. Scientific expertise in and demonstrated commitment to the development of drug delivery systems.

3. Experience in preclinical and clinical drug development.

4. Experience and ability to produce, package, market and distribute pharmaceutical products.

5. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

6. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from pre-clinical studies and clinical trials regarding the subject compounds.

7. Provide defined financial and personnel support for the CRADA to be mutually agreed upon.

8. An agreement to be bound by the DHHS rules involving human and animal subjects.

9. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

10. Provisions for equitable distribution of patent rights to any CRADA inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government and (2) an option for the collaborator to elect an exclusive or nonexclusive license to Government owned rights under terms that comply with the appropriate licensing statutes and regulations.

Dated: August 14, 1996.

Thomas D. Mays,
*Director, Office of Technology Development,
OD, NCI.*

[FR Doc. 96-22393 Filed 8-30-96; 8:45 am]

BILLING CODE 4140-010-M

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Date: September 10-11, 1996.

Time: September 10-8 am to 5 pm; September 11-8 am to adjournment.

Place: Holiday Inn, Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Mary Nekola, Ph.D., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, MSC 7180, Bethesda, MD 20892-7180, 301-496-8683.

Purpose/Agenda: To review and evaluate grant applications. The meeting will be

closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code. The applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which could constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle. (Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: August 28, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-22392 Filed 8-30-96; 8:45 am]

BILLING CODE 4140-01-M

Division of Research Grants; 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 Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Microbiological and Immunological Sciences.

Date: September 11, 1996.

Time: 11:00 a.m.

Place: NIH, Rockledge 2, Room 4190, Telephone Conference.

Contact Person: Dr. Garrett Keefer, Scientific Review Administrator, 671 Rockledge Drive, Room 4190, Bethesda, Maryland 20892, (301) 435-1152.

Name of SEP: Clinical Sciences.

Date: September 16, 1996.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 4100, Telephone Conference.

Contact Person: Dr. Jeanne Ketley, Scientific Review Administrator, 671 Rockledge Drive, Room 4100, Bethesda, Maryland 20892, (301) 435-1788.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-

93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 28, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-22391 Filed 8-30-96; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO-310-1310-01-24-1A]

Extension of Currently Approved Information Collection; OMB Approval Number 1004-0074

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is announcing its intention to request an extension of approval for the collection of information which will be used to determine the highest qualified bonus bid submitted for a competitive oil and gas or geothermal lease (Form 3000-2) and enable the BLM to complete environmental reviews in compliance with the National Environmental Policy Act of 1969 (Form 3200-9). The information supplied allows the BLM to determine whether a bidder is qualified to hold a lease and to conduct geothermal resource operations under the terms of the Mineral Leasing Act of 1920 and the Geothermal Steam Act of 1969.

DATE: Comments must be submitted on or before November 4, 1996.

ADDRESSES: Comments may be mailed to: Regulatory Management Team (420), Bureau of Land Management, 1849 C Street NW, Room 401 LS Bldg., Washington, D.C. 20240.

Comments may be sent via Internet to: WOCComment@WO0033wp.wo.blm.gov.

Comments may be hand delivered to the Bureau of Land Management Administrative Record, Room 401, 1620 L Street N.W., Washington, D.C.

Comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Gloria J. Austin, (202) 452-0340.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 1320.8(d), the BLM is required to provide a 60-day notice in the Federal Register concerning a proposed collection of

information to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

The Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 et seq.) gives the Secretary of the Interior responsibility for oil and gas leasing on approximately 600 million acres of public lands and national forests, and private lands where minerals have been reserved by the Federal Government. The Federal Onshore Oil and Gas Leasing Reform Act of 1987 was passed by Congress to require that all public lands that are available for oil and gas leasing be offered first by competitive oral bidding. The Department of the Interior Appropriations Act of 1981 (43 U.S.C. 6508) provides for the competitive leasing of the lands in the National Petroleum Reserve-Alaska (NPR-A). The Geothermal Steam Act of 1970 (30 U.S.C. 1001-1025) authorizes the Secretary of the Interior to issue leases for geothermal development. The lands available for exploration and leasing include public, withdrawn, reserved, and acquired lands administered by the Bureau of Land Management (BLM). The National Environmental Policy Act (NEPA) of 1969 established a national policy to protect the environment.

The regulations within 43 CFR Group 3100 outline procedures for obtaining a lease to explore for, develop, and produce oil and gas resources located on Federal lands. The regulations within 43 CFR Group 3200 provide for the issuance of geothermal leases and the exploration, development and utilization of Federally-owned geothermal resources. The BLM needs the information requested on the two forms to process bids for oil and gas and geothermal lands and to complete environmental reviews required by the NEPA.

The information will be used to determine the highest qualified bonus bid submitted for a competitive oil and gas or geothermal resources parcel on