ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Total hour burden
Public, including people at risk for diabetes, patients and their family members	1600	1	.25	400
Totals	1,600			400

COST TO RESPONDENTS

Type of respondents	Number of respondents	Frequency of response	Hourly wage rate	Respondent cost
Public, including people at risk for diabetes, patients and their family members	1600	1	$20.00	$8,000.00
Total				$8,000.00

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Joanne Gallivan, M.S., R.D., Director, National Diabetes Education Program, NIDDK, NIH, Building 31, Room 9A04, 31 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 494–6110 or e-mail your request, including your address to: *Joanne_Gallivan@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect received within 30 days of the date of this publication.

Dated: June 28, 2005.

Barbara Merchant,

Executive Officer, NIDDK, National Institutes of Health.

[FR Doc. 05–14491 Filed 7–21–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing and Cooperative Research and Development Agreement (CRADA): Aminoflavone Prodrug

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions described 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 in association with collaborative research via a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the National Institutes of Health. This opportunity is being offered 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 may be obtained by contacting George G. Pipia, PhD., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; telephone: 301/435–5560; fax: 301/402–0220; e-mail: *PipiaG@mail.nih.gov.*

CRADA inquiries may be addressed to Robert Wagner, M.S., M. Phil., at the Technology Transfer Branch, National Cancer Institute, 6120 Executive Boulevard, Suite 450, Rockville, MD 20852; telephone: 301/496–0477; fax: 301–402–2117; e-mail: *WagnerB@mail.nih.gov.*

Information regarding NCI drug development collaborations with the Cancer Therapy Evaluation Program can be found at *http://ctep.cancer.gov/.*

SUPPLEMENTARY INFORMATION: Scientists at the National Cancer Institute (NCI), NIH, have developed a novel anti-cancer agent, the aminoflavone prodrug (AFP–464, NSC 710464) which is a lysyl prodrug of aminoflavone (AF, NSC 686288). AFP–464 displays improved solubility in aqueous solutions over the parent compound AF and can be converted rapidly to AF in plasma. In the NCI 60-cell-line screen, both AFP–464 and AF have demonstrated anti-proliferative activity against several renal, breast and ovarian cancer cell lines. AFP–464 and AF have also demonstrated anti-tumor activity in human renal and breast carcinoma xenografts. Pharmacokinetic studies and toxicology studies of AFP–464 have been completed.

The results of the pre-clinical studies conducted by NCI have led to a decision by the NCI to initiate NCI-sponsored clinical trials of AFP–464. The Cancer Therapy Evaluation Program (CTEP), NCI expects to file an Investigational New Drug Application with the FDA for AFP–464 before the end of 2005.

Patent Portfolio: The patent portfolio for the aminoflavone compounds and the aminoflavone prodrug, claiming the compositions of matter and methods in the treatment of cancer includes issued patents and patent applications

claiming rights worldwide, as provided below (websites for patent application publications are included).

Patents and patent applications for the aminoflavone compounds, entitled ''5–Aminoflavone Derivative,'' consist of:

1. U.S. Patent No. 5,539,112 (issued 07/23/1996), (*http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=5539112.WKU.&OS=PN/5539112&RS=PN/5539112*);

2. European Patent No. 0638566 (issued 01/07/1999 and validated in GB, DE, FR, ES and IT), (*http://v3.espacenet.com/textdoc?DB=EPODOC&IDX=EP0638566&F=0*);

3. Canadian Patent Application No. 2129813 (filed 08/09/1994), (*http://patents1.ic.gc.ca/details?patent_number=2129813&language=EN*).

Patents and patent applications for the aminoflavone prodrug, entitled ''Aminoflavone Compounds, Compositions, and Methods of Use Thereof,'' consist of:

1. U.S. Patent No. 6,812,246 (issued 11/02/2004), (*http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=6812246.WKU.&OS=PN/6812246&RS=PN/6812246*);

2. European Patent Application No. 01923228.9 (filed April 6, 2001, now allowed and validated in GB, DE, FR, IT, ES, LU, BE, CH, and IE), (*http://v3.espacenet.com/textdoc?DB=EPODOC&IDX=US2004019227&F=0*);

3. Canada Patent Application No. 2405747 (filed April 6, 2001), *http://patents1.ic.gc.ca/details?patent_number=2405747&language=EN*);

4. Australia Patent Application No. 2001249940 (filed April 6, 2001), (*http://apa.hpa.com.au:8080/ipapa/view?hit=1&page=1*).

Licensing and Cooperative Research and Development Agreement Opportunity: The National Cancer Institute (NCI) seeks a collaborator to co-develop the aminoflavone pro-drug (AFP–464) for clinical use. A Cooperative Research and Development Agreement (CRADA) is the anticipated collaborative 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. A CRADA 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 can contribute facilities, staff, materials, expertise, and funds. The CRADA collaborator will also have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research. Licensing the above patent rights will be necessary to commercialize AFP–464 if clinical trials results are favorable. It is expected that a licensee to the above patent rights will become the NCI CRADA collaborator in the clinical development of AFP–464.

Those interested in this CRADA opportunity should prepare a confidential proposal and submit it to the NCI Technology Transfer Branch. Preference will be given to proposals received by the NCI within thirty days of publication of this announcement. Selection criteria for choosing the CRADA Collaborator shall include, but not be limited to: 1. Demonstrated expertise and success in clinical development of anti-cancer agents; 2. possession of the resources needed to support and perform the research and development activities to develop AFP–464 (*e.g.* facilities, personnel and expertise); 3. the ability to provide financial support for the CRADA-related Government activities; 4. the demonstration of the necessary resources to produce and supply formulated AFP–464 for all clinical trials in a timely manner; 5. the willingness to cooperate with the NCI in the timely publication of research results; 6. the willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any; and 7. the agreement to be bound by the appropriate HHS regulations relating to human subjects.

Dated: July 15, 2005.

Steven M. Ferguson,

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

[FR Doc. 05–14495 Filed 7–21–05; 8:45 am]

BILLING CODE 4140–01–U

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.

Standardizing Criteria on Cancer Biomarkers as Foundation of a Database: Creating a Common Language (Data Elements) for Cancer Biomarkers Tracking and Utilization for Professionals in Oncology Research

Mahin Khatami (NCI)

HHS Reference No. E–147–2005/0—Research Tool

Licensing Contact: Michelle A. Booden; (301) 451–7337; *boodenm@mail.nih.gov*.

Cancer biomarkers (CBs) are important biological tools in modern oncology research for diagnosis, prognosis, prevention, therapy and outcome. Biological characters of biomarkers are as diversified as their utilization potentials. Biomarkers may be proteins/peptides, glycoproteins, lipids, glycolipids, antigens/antibodies, cytokines/chemokines, receptors, enzymes, inhibitors, nutrients/metabolites, DNA/RNA mutations, etc. CBs are found in blood/serum, urine, other biological fluids, and/or tissue specimen.

The NCI has identified a common set of data elements or criteria to describe a large number of cancer biomarkers. These data elements may be used as a foundation for a cancer biomarker