

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150(e)	80	20	1,800	4	7,200
Total					7,200

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

No burden has been estimated for the recordkeeping requirement in § 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: September 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-901-1 and HCFA-1763]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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:* Revision of a currently approved collection;

Title of Information Collection: Qualification Application and Supporting Regulations in 42 CFR Section 417.408 and 417.143;

Form No.: HCFA-901-1 (OMB# 0938-0470);

Use: Prepaid health plans must meet certain regulatory requirements to be federally qualified health maintenance organizations. This application is the collection form used to obtain the information from health plans that allow HCFA staff to determine compliance with the regulations;

Frequency: Other: One-time;

Affected Public: Business or other for-profit, not-for-profit institutions, and State, Local, or Tribal Government;

Number of Respondents: 35;

Total Annual Responses: 35;

Total Annual Hours: 3,500.

(2) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Request for Termination of Premium Hospital and/or Supplementary Medical Insurance and Supporting Regulations in 42 CFR 406.28 and 407.27;

Form No.: HCFA-1763 (OMB No. 0938-0025);

Use: The HCFA-1763 is used by beneficiaries to request voluntary termination from premium hospital and/or supplementary medical insurance;

Frequency: One time only;

Affected Public: Individuals or Households, Federal Government, and State, Local or Tribal Government;

Number of Respondents: 14,000;

Total Annual Responses: 14,000;

Total Annual Hours: 5,833.

To obtain copies of the supporting statement 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 and phone number, 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 designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 28, 2000.

John P. Burke III,

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

[FR Doc. 00-23625 Filed 9-13-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Development of a Molecular Rotation Engine

An opportunity for a Cooperative Research and Development Agreement (CRADA) is available for collaboration with the NCI Intramural Division of Basic Sciences for the development of an ATP-driven, molecular-based rotation engine. The opportunity is open to a multi or single party collaboration that would require the input of molecular biology and genetic engineering experience on the part of the potential collaborator or collaborators.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of Opportunity for Cooperative Research and Development Agreement.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a biotechnology, pharmaceutical, or other company that possesses the ability to assist in the development and commercialization of the described technology. CRADA proposals for development of this technology should include the development of a prototype. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA will include the rapid publication of research results and timely commercialization of any products that result from the research. The CRADA Collaborator or Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Mr. Kevin Brand, Technology Development & Commercialization Branch, National Cancer Institute—Frederick Cancer Research and Development Center, Fairview Center, 1003 West Seventh Street, Room 502, Frederick, MD 20852, Telephone: (301) 846-5222; Facsimile: (301) 846-6820.

EFFECTIVE DATE: Organizations must submit a proposal summary of one page or less, to NCI on or before November 13, 2000. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The National Cancer Institute (NCI) of the National Institutes of Health (NIH) has a pending patent application related to the development of a molecular-based rotation engine. The engine is constructed of two cylinders, one inner and one outer whose inner surfaces are coated with oriented mobility or contractile proteins. In the presence of ATP the cylinders rotate relative to each other. Speed of relative rotation is controlled by the concentration of ATP or by nesting a series of cylinders inside each other. Power is controlled by

adjusting the length of the cylinders. One advantage of this technology over other macroscopic motors is that it can be used to supply power to prosthetic implants and medical devices without the drawbacks associated with conventional power sources. Other advantages are that the motor operates at room temperature, and that fuels can be prepared from sugar, so the motor does not contribute to carbon dioxide pollution and the waste products are biologically safe. The NCI, in accordance with the regulations governing the transfer of agents which the Government has taken an active role in developing (37 CFR 404.8), is seeking a biotechnology, pharmaceutical or other similarly situated company which can develop a working model of this molecular engine and has the ability to make it commercially available. Those potential collaborators interested in reviewing NCI's pending patent application on this technology should contact J.P. Kim at the National Institutes of Health, Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852, Telephone (301) 496-7056; Facsimile (301) 496-0220.

The role of the National Cancer Institute in this CRADA may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience related to the development of a prototype molecular-based engine.

1. Providing collaborator or collaborators access to confidential information relating to the pending patent application which embodies this technology.

2. Planning research studies and interpreting research results.

3. 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 for the development of a prototype molecular-based engine.

Collaborators must have expertise in standard molecular biology: Gene construction, cloning and protein isolation. Experience in genetic engineering is essential. Other areas of expertise would include silicon micromachining and past work in nanotechnology.

2. Providing technical and financial support to facilitate scientific goals, as well as personnel and laboratory space.

3. Assume responsibility for the commercialization, marketing and distribution of such a molecular engine should a sound prototype be developed.

4. Planning research studies and interpreting research results.

5. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on the research and development of this technology. The ability to collaborate with NCI can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.

2. The demonstration of adequate resources to perform the research and development of this technology (*e.g.* facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. 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.

4. The demonstration of expertise in the commercial development and production of products related to this area of technology.

5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

7. 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.

8. The willingness to accept the legal provisions and language of the CRADA with only minor modification, if any. These provisions govern the distribution of 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: September 3, 2000.

Kathleen Sybert,

Branch Chief, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.

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