used to support the expiration date in order to ensure that the expiration date is accurate.

The respondents to this collection of information are domestic and foreign condom manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.435	45	1	45	96	4,320

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

The number of domestic establishments was estimated by reviewing the FDA data base of registered medical device manufacturers to arrive at 5 domestic and 40 foreign condom manufacturers. Based upon conversations with condom manufacturers, FDA field personnel, and comments received from the public during this collections initial approval, FDA determined the number hours to complete labeling and testing of condoms to be 96 hours per respondent.

Dated: June 15, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–15865 Filed 6–22–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education (CHGME) Program Conference

On June 19, 2000, the Health Resources and Services Administration (HRSA) published a notice in the **Federal Register** announcing the Children's Hospitals Graduate Medical Education (CHGME) Program (65 FR 37985). Interested parties are invited to attend a briefing conference on July 7, 2000, from 1 p.m. to 3 p.m. EDT in conference room D in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Parties may also participate in the conference by telephone. To do so, dial: 800–545–4387 or 700–991–1738 (for Federal Government employees), then enter the access code ID# 28353. Telephone participants should call by 12:45 p.m.

The conference is to provide information on the topics contained in the CHGME notice: proposed eligibility criteria, funding factors and methodology, and performance measures. It will include a question and answer period.

For additional information call or write to: F. Lawrence Clare, telephone: (301) 443–7334; Division of Medicine and Dentistry, Bureau of Health Professions, Room 9–A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; *lclare@hrsa.gov.*

Dated: June 19, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–15901 Filed 6–22–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Development of Innovative Idiotype Tumor Vaccines

Multiple opportunities are available for collaboration with the National Cancer Institute (NCI), Division of Clinical Sciences, for the pre-clinical and clinical development of protein and/or DNA-based idiotypic vaccines using novel formulations, adjuvants or delivery systems and directed against low-grade and intermediate B-cell lymphomas, mantle cell lymphomas or chronic lymphocytic leukemias (CLL). It is anticipated that because of the magnitude and diversity of these projects the collaboration(s) will take the form of multiple Cooperative Research and Development Agreements (CRADAs). The collaboration(s) may involve any aspect of the therapeutic development of these tumor vaccines from basic scientific inquiry to late stage clinical trials.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for Cooperative Research and Development Agreements.

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) is seeking pharmaceutical or biotechnology companies which can effectively collaborate on the scientific and commercial development of idiotypic tumor vaccines for treatment of low-grade and intermediate B-cell lymphomas, mantle cell lymphoma or chronic lymphocytic leukemia (CLL). The goal of the collaboration(s) will be the development of novel vaccine strategies to elicit an immune response directed against autologous idiotypic surface immunoglobulin derived from these tumors. Any CRADA for further development of this technology that focuses on preclinical or clinical studies of idiotypic vaccines for treatment of the indicated diseases will be considered. The CRADA would have an expected duration of three (3) to five (5) years. The goals of the CRADA will include the rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research. The CRADA 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 Dr. Thomas M. Stackhouse, 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. Scientific Inquiries may be directed to Dr. Larry Kwak, M.D., Ph.D., Senior Investigator, Division of Clinical Sciences, National Cancer Institute, Bldg. 567, Room 205, Frederick, MD 21702–1201, Telephone: (301) 846–1607; Facsimile: (301) 846–6107.

EFFECTIVE DATE: Organizations must submit a proposal summary preferably two pages or less, to NCI within 90 days from date of this publication. Guidelines

for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial discussions have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The NCI has established the anti-tumor effects of protein-based immunologic anti-idiotype antibodies for lymphoma-specific vaccination in both animal studies and human clinical trials evaluating idiotype vaccines against B-cell lymphomas. B-cell tumors are composed of clonally-expanded cells synthesizing a single antibody molecule containing unique variable regions in the heavy and light chains known as idiotypic determinants. B-cell lymphomas consist of mature resting and reactive lymphocytes, which typically synthesize and express immunoglobulin on the cell surface. Idiotypic determinants of the surface immunoglobulin of B-cell malignancies therefore, comprise tumor-specific antigens that can be used to elicit a specific immune response against B-cell lymphoma. Immunization against idiotypic determinants on malignant B cells prevents tumor growth and antagonizes the growth of established tumors in several syngeneic tumor models. Studies conducted at the NCI have also demonstrated that idiotype specific immune responses against an autologous antigen could be induced in patients with B-cell lymphoma (New Engl. J. of Med. 327:1209–1215, 1992).

In a recent clinical study, NCI investigators demonstrated that an idiotypic protein vaccine against B-cell lymphoma administered in combination with granulocyte-macrophage colony-stimulating factor (GM–CSF), exerts an anti-tumor effect in patients with B-cell lymphoma as measured by the eradication of residual tumor cells bearing a t(14:18) translocation detectable by PCR. The clearance of residual tumor cells from the blood and the presence of tumor specific cytotoxic T-cells correlated with long-term disease free survival in these patients. Based on the results of these studies, the NCI is currently conducting a definitive multi-center Phase III clinical trial of idiotype vaccines against follicular B-cell lymphoma. In addition, results of Phase I/II clinical studies evaluating the effectiveness of protein-based immnoglobulin idiotype vaccines in the treatment of multiple myeloma have also provided support for the use of idiotypic vaccines as a cancer therapeutic. The NCI is currently seeking partners to collaborate in extending the development of idiotype tumor vaccines to additional tumor types specifically, low-grade and intermediate B-cell lymphomas, mantle cell lymphoma and chronic lymphocytic leukemia (CLL). In addition, the NCI is interested in evaluating novel formulations, adjuvants or delivery systems for idiotypic vaccines against any of the indicated diseases, including B-cell lymphoma and myeloma.

The NCI specifically seeks corporate partner(s) with the ability to collaborate in the development of any of these therapeutic applications. Since idiotypic determinants are tumor-specific, the vaccines must be custom-made for each patient. Collaborators will be selected based upon the scientific merit and intellectual contributions brought to each individual project(s) as well as their demonstrated expertise in vaccine production and clinical monitoring. Potential collaborators should have experience in preclinical and clinical drug development; experience in the monitoring, evaluation and interpretation of data from investigational agent clinical studies; or experience in areas that represent an extention of these studies to include new formulations, or approaches to vaccine delivery, such as the development of DNA-based idiotype vaccines.

The role of the National Cancer Institute in the CRADA(s) may include but is not limited to the following:

1. The NCI will provide intellectual, scientific, and technical expertise and experience related to the development of idiotype vaccines.

2. The NCI will continue preclinical and clinical development of these vaccines and will make data available to the collaborator as appropriate.

3. NCI will collaborate in the design of experiments and the evaluation of results.

4. Agents developed under a pre-clinical CRADA may proceed to clinical development under NCI-sponsored clinical trials if warranted.

The role of the CRADA Collaborator may include, but is not limited to the following:

1. Providing scientific development strategy and financial and other support for the collaborative preclinical development of vaccines for new disease indications or for development of novel methodologies.

2. Providing significant intellectual, scientific, and technical expertise or experience to the development of processes required for GMP vaccine production of selected vaccine candidates.

3. Participating in clinical development leading to FDA approval and marketing through participation on a Steering Committee established to guide the commercialization of successful vaccines.

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

1. The scientific merit and intellectual contribution of the Collaborator as outlined in the project proposal. Potential collaborators are urged to submit proposals which focus on particular areas of expertise and which clearly outline a development and commercialization plan.

2. The ability to collaborate with NCI on the research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas that indicate the ability to contribute intellectually to the ongoing research and development of idiotype vaccines.

3. 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.

4. 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.

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

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.

Dated: June 5, 2000.

Kathleen Sybert,

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

[FR Doc. 00–15939 Filed 6–22–00; 8:45 am]

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