Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Laura Oliven, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 4, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–23887 Filed 9–9–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request

A Pilot Study of *Helicobacter pylori* Infection and Mode of Transmission Among Children in Linqu County, Shandong Province, China.

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: *Title:* A Pilot Study of *Helicobacter pylori* Infection and Mode of Transmission Among Children in Linqu County, Shandong Province, China. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The agency conducts and funds studies examining risk factors for infectious and chronic diseases that may be related to risk of cancer. This information collection is needed to evaluate data collection methods and the quality of the data collected prior to implementation with a larger study population. The data collection effort is needed to identify personal practices and environmental conditions which appear to contribute to H. pylori transmission. Questionnaire data obtained from mothers will be linked with existing H. pylori status data to investigate factors that may influence the prevalence of H. pylori infection in Linqu County children. *Frequency of Response:* One time. *Affected Public:* Individuals or households. *Type of Respondents:* Parents. The annual reporting burden is as follows: *Estimated Number of Respondents:* 98; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .33; *and Estimated Total Annual Burden Hours Requested:* 32. The annualized cost to respondents is estimated at: $21.33. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Linda Morris Brown, MPH, Assistant Director for Epidemiology and Biostatistics, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, 6130 Executive Blvd., Executive Plaza North, Room 415, Bethesda, MD, 20892, or call non-toll-free number (301) 496–4153 or E-mail your request, including your address to: brownl@epndce.nci.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before November 10, 1997.

Dated: September 4, 1997.

Nancie L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 97–23899 Filed 9–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the Development of New Targeted Drugs, Made Partly of Entities Provided by the National Cancer Institute (NCI), as Treatments for Patients With Cancer

The NCI is looking for multiple CRADA Collaborators to develop independently different aspects of their targeted drug technology with the goal of moving candidates into clinical trials.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for cooperative research and development.

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 Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies or academic institutions to create, optimize and test new targeted drugs as therapeutics for cancer.

Any CRADA for the biomedical use of this technology will be considered. The CRADAs would have an expected duration of one (1) to five (5) years. The goals of the CRADAs 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 CRADAs.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Thomas M. Stackhouse, Office of Technology Development, National Cancer Institute-Frederick Cancer Research and Development Center, P.O. Box B, Frederick, MD 21702–1201, Telephone: (301) 846–5465, Facsimile: (301) 846–6820.

EFFECTIVE DATE: Organizations must submit a confidential proposal summary preferably one page 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 confidential discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists are developing a variety of novel targeted drugs defined as a conjugated molecule consisting of a specific binding moiety, such as a monoclonal antibody, a receptor ligand or a similar construct, and a natural product or synthetic cytotoxic moiety which may include, but not be limited to the broad category of toxins and drugs. The specific binding and cytotoxic moieties would be joined by appropriate linker molecules. The NCI can provide a variety of natural product cytotoxic drugs either in the unaltered state or chemically-modified (to facilitate conjugation) as starting substances for the creation of new targeted drug agents. In addition, a limited number of monoclonal antibodies which can be used in this drug development effort are available from the NCI. The NCI can also provide the chemical expertise to modify agents, as well as the resources to test newly constructed agents in an *in vitro* cell line screen. Publications outlining these developments are available on request, and descriptions of other (unpublished) advances can be obtained from Dr. Stackhouse via a Confidential Disclosure Agreement.

DHHS now seeks collaborative arrangements for the creation, optimization, evaluation and possible clinical exploitation of these agents. A Cooperative Research and Development Agreement (CRADA) will be established to provide for distribution of intellectual property rights developed under the Agreement. The successful CRADA collaborator will provide expertise and experience in the preparation of targeted drugs, and will prepare one or more targeted drug candidates using starting substances provided jointly by the NCI and the CRADA collaborator. For targeted drug candidates selected for clinical trials, the Collaborator will also provide the necessary resources and expertise to perform tests to determine the drug candidate's physicochemical makeup, biological activity, stability and other characteristics necessary for filing an Investigational New Drug (IND) application with the FDA. The NCI will provide starting substances as well as consultation and expertise on drug preparation and development. Also, the NCI may elect to provide resources for preclinical and/or clinical evaluation, subject to future review and approval. CRADA aims will include rapid publication of research results as well as timely clinical evaluation and exploitation of any commercial opportunities.

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

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Providing the Collaborator with samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies .

3. Planning research studies and interpreting research results.

4. Additional support for preclinical and/or clinical development of the targeted drug candidate(s) derived from this CRADA. Commitment of substantial resources would require specific review and approval by the Decision Network Committee of the NCI's Division of Cancer Treatment, Diagnosis, and Centers (DCTDC). These resources may include:

(A) *In vitro* testing in the DCTDC cell line screen.

(B) Assistance with design and conduct of preclinical *in vivo* efficacy experiments.

(C) Toxicology experiments.

(D) Provision of additional starting materials for use by the Collaborator in preparing final targeted drug product.

(E) IND filing and sponsorship of clinical trials.

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.

2. Planning research studies and interpreting research results.

3. Providing samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies.

4. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.

5. Production, by current Good Manufacturing Practices (cGMP), purification, vialing, product release, and post-release testing of targeted drug candidates for clinical trials.

6. 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 further research and development of this technology. This ability 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 modifications, 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: August 25, 1997.

Kathleen Sybert,

Acting Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 97–23901 Filed 9–9–97; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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