

Following publication of the notice of opportunity for a hearing and in accordance with the procedures set forth in parts 12 and 601 (21 CFR parts 12 and 601), on June 15, 1994, the Responsible Head of Central Georgia submitted a request for a hearing to the Dockets Management Branch and, on July 15, 1994, provided additional supplemental information to justify the request for a hearing.

While the request for a hearing was pending, the owner and former Responsible Head of Central Georgia informed the agency by letter dated July 12, 1996, that Central Georgia had closed its facility on June 24, 1996, and ceased operations effective June 25, 1996, and was voluntarily surrendering both the establishment and product licenses. FDA notified Central Georgia by letter of August 21, 1996, that the licenses had been revoked.

Based on the voluntary surrender of U.S. License No. 0649-001, Central Georgia's request for a hearing on the issue of license revocation became moot. Central Georgia effectively waived an opportunity for a hearing on the matter (§ 601.5(a)).

Accordingly, under § 601.5(a), section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 0649-001) and the product license issued to Central Georgia Plasma Lab, Inc., for the manufacture of Source Plasma were revoked, effective August 21, 1996.

This notice is issued and published under § 601.8 and the redelegation at 21 CFR 5.67.

Dated: August 25, 1997.

Mark Elengold,
Acting Deputy Director, Center for Biologics Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: AIDS Drug Assistance Program [ADAP]: Monthly Client Utilization and Program Expenditure Assessment Project—NEW—State AIDS Drug Assistance Programs [ADAP], funded under section 2611 of the Public Health Service Act (commonly known as Title II of the Ryan White Comprehensive AIDS Resources Emergency [CARE] Act) are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medications that prevent serious deterioration of health arising from HIV disease, including prevention and treatment of opportunistic diseases.

Due to the increasing need for pharmaceuticals among uninsured and underinsured low-income individuals who are HIV+ or diagnosed with AIDS, and recognizing the importance of program planning and budget forecasting to maximize resources, the Division of Service Systems [DSS], Health Resources and Services Administration [HRSA], proposes to collect relevant client utilization data and program expenditure information on a voluntary monthly reporting basis from State ADAPs. This effort is designed to assist Title II grantees, State ADAPs, the DSS/HRSA funding agency staff, and policymakers at both the Federal and State level to better understand the level of client need for medications that the programs are functioning under and the resources used to meet the needs, and to provide indicators of where future action may be required and the most appropriate response(s).

A report is proposed that will collect monthly data on the level of expenditures and client utilization of services. In addition, the report will provide a forum for tracking the most current changes in each State ADAP with respect to available funding, eligibility criteria, clinical guidelines, and formulary changes. On a quarterly basis, the report will also request the prices of eight specified pharmaceuticals dispensed by each program. The individual State reports will be compiled into summary reports and distributed back to grantees and State ADAPs on a monthly basis, and will be available for use by HRSA and the Office of Management and Budget. These results will be used to guide program planning, to formulate budget recommendations, and to monitor the balance between available resources and State needs. The burden estimates are as follows:

| Type of form | Number of respondents | Responses per respondent | Hours per response | Total burden hours |
|--|-----------------------|--------------------------|--------------------|--------------------|
| ADAP Monthly Update | 54 | 12 | 1 | 648 |
| ADAP Quarterly Drug Pricing Update | 54 | 4 | 1 | 216 |
| Total | 54 | 16 | 1 | 864 |

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]

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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 Linq 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 Linq 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 Linq 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.

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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