Atlanta, GA 30341–4146, Telephone number (770) 488–2753, E-mail address gcg4@cdc.gov.

For program technical assistance, contact: Linda Moyer, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Rickettsial Diseases, Hepatitis Branch, 1600 Clifton Road, NE, M/S G–37, Atlanta, GA 30333, Telephone: (404) 371–5460, E-mail address: lam1@cdc.gov.

Dated: April 26, 2000.

Henry S. Cassell, III,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 00056]

Development and Testing of New Antimalarial Drugs; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for the Development and Testing of New Antimalarial Drugs. CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010'', a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Immunization and Infectious Diseases. For the conference copy of ''Healthy People 2010'', visit the internet site http://www.health.gov/healthypeople.

The purpose of this program is to support research projects to develop and test new antimalarial drugs. Projects may include, but not be limited to a range of activities such as identifying promising agents, purifying or creating them, optimizing them for clinical use, and testing them in in vitro and in vivo systems. Applications may include components to develop national centers of excellence that would serve as national repositories of expertise and experience. For example, an application to establish a national center of excellence for computer-assisted drug design for malaria and for screening potential candidate drugs could be considered. This might include high throughput testing of potential antimalarial compounds. Second and third year plans may include clinical trials.

B. Eligible Applicants

Assistance will be provided only to the University of Mississippi. No other applications are solicited.

The FY 2000 United States Senate Labor-Health and Human Services Appropriations Report: Report 106–166 (S 1650), recognized the unique qualifications of the consortium of the University of Mississippi Laboratory for Applied Drug Design and Synthesis and the Tulane University Center for Infectious Diseases for carrying out the activities specified in this cooperative agreement.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $5,000,000 is available in FY 2000 to fund one award. It is expected the award will begin on or about August 30, 2000, and will be made for a 12-month budget period within a project period of up to three years. The funding estimate may change.

A continuation award within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities) and CDC will be responsible for conducting activities under 2. (CDC Activities):

1. Recipient Activities

a. Develop and implement strategies for acquiring or developing new antimalarial compounds. This may include the use of natural products, computer-aided drug design, and development of analogs of known drugs.

b. Develop and implement a rational approach to selecting promising drug candidates.

c. Develop strategies and capacity to produce adequate quantities of compound, for example, by using an automated organic synthesizer or other technology.

d. Develop and implement a systematic approach to in vitro testing of drug candidates. Develop and evaluate in vitro systems for drug testing where results allow prediction of the risk of development of in vivo resistance and the rate at which resistance is likely to develop.

e. Conduct in vivo testing of promising candidates, including the use of primate models.

f. Develop a plan for enhancing commercial interest in promising drugs.

g. Disseminate results of research.

2. CDC Activities

a. Provide technical assistance in the design and conduct of the research.

b. Provide selected laboratory tests, as necessary or appropriate.

c. Provide biological materials (e.g., strains, reagents, etc.) as necessary or appropriate.

d. Upon request, assist in the development of assays for evaluating pharmacokinetics of new antimalarial drugs.

e. Upon request, provide in vitro testing for P. vivax, as well as in vivo testing for malaria parasites.

f. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 10 double-spaced pages printed on one side, with one inch margins and unreduced font.

F. Submission and Deadline

Application

Submit the original and five copies of PHS 398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit.

On or before June 1, 2000, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' Section of this announcement.

G. Evaluation Criteria

The application will be evaluated against the following criteria by an independent review group appointed by CDC.

1. Background and Need (10 points)

Extent to which applicant demonstrates a clear understanding of the background, purpose, and objectives of the focus area being addressed. Extent to which applicant demonstrates that the proposed project addresses the purpose. Extent to which the applicant demonstrates that the proposed program collaborates with and does not duplicate existing rational development efforts.

2. Capacity (45 points)

Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. If applicable, extent to which applicant includes letters of support from participating non-applicant organizations, individuals, etc., and the extent to which such letters clearly indicate the author's commitment to participate as described in the operational plan.

3. Objectives and Technical Approach (45 points total)

a. Extent to which applicant describes measurable and time-phased objectives of the proposed project which are consistent with the purpose of the focus area being addressed. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all recipient activities for the specific programmatic focus area being addressed. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the approach/methods are feasible, appropriate, and adequate to accomplish the objectives.

Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. Extent to which applicant clearly describes collaboration with CDC and/or others during various phases of the project. (25 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives. (5 points)

d. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes (a) the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation, (b) the proposed justification when representation is limited or absent, (c) a statement as to whether the design of the study is adequate to measure differences when warranted and (d) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits. (5 points)

4. Budget (not scored)

Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

5. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

6. Animal Subjects (not scored)

Does the application adequately address the requirements of PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. progress reports (semiannual);

2. financial status report, no more than 90 days after the end of the budget period; and

3. final financial and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–3 Animal Subjects Requirements

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(1)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(1)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC Homepage Internet address-http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

To obtain additional information, contact: Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone number 770–488–2753, Email address gcg4@cdc.gov

For program technical assistance, contact: John W. Barnwell, Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 4770 Buford Highway, N.E., Atlanta, GA 30333, Telephone number 770–488–4528, Email address wzb3@cdc.gov

Dated: April 26, 2000.

Henry S. Cassell, III,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1246]

Agency Information Collection Activities: Proposed Collection; Comment Request; Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of