

expected that the award will begin on or about September 15, 2003, 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.

#### *Recipient Financial Participation*

Matching funds are not required for this program.

#### *Funding Preferences*

Applications for new studies are encouraged. Funding preference may be given to the competing continuation application over applications for programs not already receiving support under the existing program. The current awardee has implemented strategies and begun developing and testing for treatment of infectious diseases using natural products. This research requires continued support to become fully developed and to realize the benefits of continued product development.

### **E. Program Requirements**

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

#### *1. Recipient Activities*

a. Develop and implement strategies for selection of emerging infectious disease(s) that affect humans, and for acquiring or developing new medications for treatment of those diseases using natural products. This includes studying the pharmacologic and biologic characteristics of natural product structures and analogs and designing molecules using computer methods for known biochemical targets.

b. Use combinatorial methods to optimize anti-infectives resulting from these approaches.

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.

e. Conduct in vivo testing of promising candidates if appropriate.

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

g. Publish and disseminate the research results.

#### *2. CDC Activities*

a. Assist in the design and conduct of the research through consultations and meetings between CDC experts and the Recipient.

b. Perform selected in vivo and ex vivo laboratory tests available at CDC for drug activity and efficacy on parasitic protozoan parasites. These assays will be performed on promising compounds that have undergone initial basic in vitro biochemical and computer modeling screens by the Awardee.

c. Provide biological materials from the CDC repository in the form of various parasitic protozoan species with strains of variable geographical origin, genetic background and phenotypic differences and are necessary to analyze the full range of drug efficacy of promising chemotherapeutic compounds to be developed.

d. Assist in the development of assays for evaluating pharmacokinetics of new drugs.

e. 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.

### **F. Content**

#### *Applications*

The Program Announcement title and number must appear in the application. 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 pages, double-spaced, printed on one side, with one-inch margins, and unredacted 12-point font.

The narrative should consist of capacity, objectives and technical approach, background and need, evaluation plan, measures of effectiveness and budget.

### **G. Submission and Deadline**

#### *Application Forms*

Submit the signed original and two copies of PHS 398 (OMB Number 0925-0001). Adhere to the instructions on the Errata Instruction Sheet (posted on the CDC web site) for PHS 398. Forms are available at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>. If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may

contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) at: 770-488-2700. Application forms can be mailed to you.

#### *Submission Date, Time, and Address*

The application must be received by 4 p.m. Eastern Time June 15, 2003.

Submit the application to: Technical Information Management-PA03056, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146. Applications may not be submitted electronically.

#### *CDC Acknowledgment of Application Receipt*

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

#### *Deadline*

Applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

### **H. Evaluation Criteria**

#### *Application*

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria: