## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Antimalarial Drug Resistance and Prevention of Malaria During Pregnancy; Notice of Intent To Fund Single Eligibility Award

**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2005 funds for a cooperative agreement program to increase the epidemiological and operational data generated in the West African sub-region upon which policy makers can base their decisions and bring cutting edge malaria control tools from the bench to the field. The Catalog of Federal Domestic Assistance number for this program is 93.283.

**B. Eligible Applicant**

Assistance will be provided only to the Malarial Research and Training Center (MRTC), Department of Epidemiology and Parasitic Diseases, Faculty of Medicine and Dentistry, University of Bamako, Mali.

The Malaria Research and Training Center (MRTC) is the only institution in West Africa that has the experience and infrastructure required. The MRTC designed and developed the Genotype Resistance Index (GRI), a crucial component of the proposed work. MRTC has also conducted the only full scale randomized controlled trial comparing chemoprophylaxis and intermittent preventive treatment for the prevention of malaria during pregnancy. They have demonstrated through this and other field-based and laboratory-based research projects that they are capable of executing complex scientific malaria research. MRTC is housed under the Department of Epidemiology and Parasitic Diseases, Faculty of Medicine, Pharmacy, and Dentistry, University of Bamako, Mali. The MRTC was founded in 1992 to conduct laboratory and field research related to malaria. Units within MRTC include Entomology and Molecular Biology, Vector Ecology, Malaria during Pregnancy, Transmission Blocking Vaccine Unit, GIS Unit, Parasite Epidemiology, Malaria Vaccine Development Unit, Biostatistics and Data Management, Drug Resistance/Molecular Biology, Parasite Immunology and Immunogenetics, Parasite Molecular Biology, and Informatics. Because of its institutional linkages with the Ministry of Health, including the National Malaria Control Program, MRTC is able to share its research findings and work with the Ministry of Health to adapt them into policy and programs. For more than a decade, MRTC has been working with all levels of the Ministry of Health to conduct health research. MRTC conducts its own data entry and has developed and built data management and analytic capacity within the Center. The team at MRTC has extensive experience in the conduct of in vivo antimalarial drug efficacy studies, supporting laboratory investigations (molecular marker identification, measurement of antimalarial drug levels, identification of P. falciparum phenotype, and in vitro efficacy studies), and the conduct of malaria during pregnancy research. MRTC scientists and collaborators have numerous published scientific papers indicating the scientific soundness of research conducted by the Center.

The combination of access and an institutional linkage to the Ministry of Health, experience conducting antimalarial drug resistance work in Mali, equipment for the conduct of polymerase chain reaction (PCR), laboratory expertise in P. falciparum antimalarial drug resistance marker identification, international stature in research on malaria during pregnancy, experience in conducting trials regarding malaria during pregnancy in Mali, the expertise to read placental malaria blood slides, an infrastructure capable of data management and analysis, and a reputation for conducting sound scientific work makes MRTC the only organization with these attributes and the only vendor who can perform the necessary work.

**C. Funding**

Approximately $100,000 is available in FY 2005 to fund this award. It is expected that the award will begin on or before June 1, 2005 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

**D. Where To Obtain Additional Information**

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For technical questions about this program, contact: Dr. Trudy Messmer, Scientific Review Administer, 1600 Clifton Road, MS C–19, Atlanta, GA 30333, Telephone: (404) 639–3770, E-mail: *TMessmer@cdc.gov.*

Dated: March 25, 2005.

**William P. Nichols,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 05–6344 Filed 3–30–05; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Mining Occupational Safety and Health Research, Request for Application OH–05–005

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Mining Occupational Safety and Health Research, Request for Application OH–05–005.

*Times and Dates:* 6 p.m.–8 p.m., April 19, 2005 (Closed). 8 a.m.–5 p.m., April 20, 2005 (Closed). 8 a.m.–5 p.m., April 21, 2005 (Closed).

*Place:* Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, VA 22314, telephone (703) 684–5900.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to Mining Occupational Safety and Health Research, Request for Application OH–05–005.

*Contact Person For More Information:* George Bockosh, MS, Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, National Personal Protective Technology Laboratory, 626 Cochrans Mill Road, Pittsburgh, PA 15236, Telephone (412) 386–6465.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 25, 2005.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 05–6345 Filed 3–30–05; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Cardiovascular and Renal Drugs Advisory Committee; Cancellation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is canceling the meeting of the Cardiovascular and Renal Drugs Advisory Committee scheduled for April 5, 2005. This meeting was announced in the **Federal Register** of March 9, 2005 (70 FR 11678).

**FOR FURTHER INFORMATION CONTACT:** Cathy A. Groupe, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: *Groupc@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 3014512533.

Dated: March 24, 2005.

**Sheila Dearybury Walcoff,**

*Associate Commissioner for External Relations.*

[FR Doc. 05–6331 Filed 3–25–05; 3:50 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Science Board to the Food and Drug Administration; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Science Board to the Food and Drug Administration.

*General Function of the Committee*: The Board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the Board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs

*Date and Time*: The meeting will be held on April 15, 2005, 8:30 a.m. to 5 p.m.

*Location*: Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

*Contact Person*: Jan Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, e-mail: *jjohannessen@fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The Board will hear about and discuss the following topics: (1) The agency's pre- and postmarketing safety programs for drugs and biologics and (2) Good Manufacturing Practices for vaccines, blood, and cell, tissue, and gene products.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 8, 2005. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 8, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jan Johannessen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 24, 2005.

**Sheila Dearybury Walcoff,**

*Associate Commissioner for External Relations.*

[FR Doc. 05–6333 Filed 3–25–05; 3:51 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for AGRYLIN (anagrelide), CLOLAR (clofarabine), and DIFLUCAN (fluconazole). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

**ADDRESSES:** Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

**FOR FURTHER INFORMATION CONTACT:** Grace Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, e-mail: *carmouzeg@cder.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for AGRYLIN (anagrelide), CLOLAR (clofarabine), and DIFLUCAN (fluconazole). The summaries are being made available