were used to ensure sufficient progress towards achievement of proposed goals and objectives are discussed. The extent to how HTC performance sites were selected is discussed. The extent that the types, frequency, and methods of evaluation were used are described. The extent to how the above information will be used to improve or redirect program operations is explained.

5. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

6. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects:

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. annual progress report, no more than 90 days after the end of the budget period;

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

3. final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist with a copy to the Project Officer 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–7 Executive Order 12372 Review
AR–8 Public Health System Reporting Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a)(42 U.S.C. 241 (a)) and 317(k)(2)(42 U.S.C. 247b(k)(2)) of the Public Health Service Act, 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 home page Internet address—http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To obtain business management technical assistance, contact: Merlin Williams, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Mailstop K–75, Atlanta, GA 30341–4146, Telephone number: 770–488–2765, E-mail: mqw6@cdc.gov.

For program technical assistance, contact: Sally O. Crudder, Director, Hemophilia Treatment Center Program, Hematologic Diseases Branch, National Center for Infectious Diseases, Centers for Diseases Control and Prevention, 1600 Clifton Road, Mailstop E–64, Atlanta, GA 30333, Ph: 404–371–5270 or 5903, Email: sic4@cdc.gov

Dated: April 30, 2001.

John L. Williams,

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

[FR Doc. 01–11217 Filed 5–3–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01071]

National Health Promotion and Information Center for People With Paralysis; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program to establish a National Health Promotion and Information Center (NHPIC) for People with Paralysis.

The purpose of this cooperative agreement is to develop and expand national efforts for the prevention of secondary conditions and complications, and to improve outcomes and the quality of life for people living with paralysis from multiple causes.

B. Eligible Applicant

Assistance will only be provided to the Christopher Reeve Paralysis Foundation. No other applications are solicited. FY 2001 Federal appropriations specifically direct CDC to award funds to this organization.

C. Availability of Funds

Approximately $1,568,000 is available in FY 2001 to fund this award. It is expected that the award will begin on or about September 30, 2001, and will be made for a 12 month budget period within a one year project period.

D. Where To Obtain Additional Information

This and other CDC announcements may be found on the CDC home page on the Internet at: http://www.cdc.gov.

To obtain business management technical assistance may be obtained from: Nancy Pillar, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mailstop E–13, Atlanta, Georgia 30341–4146, Telephone: (770) 488–2710, E-Mail address: nfp6@cdc.gov.

General program assistance can be obtained from: Joseph B. Smith, Senior Project Officer, Disability and Health Branch, National Center for Birth Defects and Developmental Disabilities, Disability and Health Branch, 4770 Buford Highway, Building 101, Mailstop F–35, Atlanta, Georgia 30341, Telephone: (770) 488–7082, E-Mail address: jos4@cdc.gov.

Dated: April 30, 2001.

John L. Williams,

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

[FR Doc. 01–11216 Filed 5–3–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01072]

Public Health Laboratory Biomonitoring Planning Grant; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a grant program to promote planning for the development, implementation, and expansion of State-

based biomonitoring programs to help prevent disease resulting from exposure to toxic substances. This program addresses ''Healthy People 2010'' focus areas of Environmental Health and Public Health Infrastructure.

In this announcement, the term ''biomonitoring'' refers to the assessment of exposure to toxic substances in people by the laboratory measurement of these substances (or their metabolites) in specimens from humans such as blood, urine and saliva. Biomonitoring measurements assess the concentration of the toxic substance in people and are often referred to as ''internal dose'' measurements.

Biomonitoring measurements can assess the exposure of a single person or by aggregating data of many people, a population. Biomonitoring measurements complement environmental measurements of toxic substances in air, water, food, soil and dust. Specific uses of biomonitoring measurements in public health include:

1. To measure the prevalence of elevated levels of toxic substances in a population group (e.g., the prevalence of blood lead levels ≥ 10 μg/dL in children living in an inner-city environment);

2. To determine levels of exposure in population groups who may be at increased risk of exposure;

3. To provide levels of human exposure in studies examining the relationship between exposure to a toxic substance (or toxic substances) and adverse health effects;

4. To determine whether levels of toxic substances are higher in potentially more vulnerable population groups such as children, the elderly, or women of childbearing age than in the general population;

5. To track over time, trends in the levels of exposure of a population group to specific toxic substances (e.g., levels of exposure to mercury in a population who consume fish as a major portion of their diet);

6. To assess the effectiveness of public health efforts to reduce the exposure of specific populations to toxic substances.

For biomonitoring measurements to be effective in addressing these public health needs, they should be accurate, precise, sensitive, specific, rugged, and have adequate throughput to complete measurements in a timely manner. For more information about the concept of biomonitoring, please see the references at the website: http://www.cdc.gov/nceh/publications/at-a-glance/Biomonitor/Default.htm

To effectively apply biomonitoring measurements, laboratories must interface with other public health partners, including physicians, epidemiologists, and health professionals at the State and local levels, in academic centers, and in communities. In addition, collaboration with other public health laboratories can be beneficial.

B. Eligible Applicants

Applications may be submitted only by public health laboratories of States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

In some States, territories, and protectorates, environmental health testing and biomonitoring responsibilities are under the jurisdiction of an agency other than the Public Health Laboratory. In those cases, application for funding under this program announcement will be accepted from other agencies, provided that the Public Health Laboratory in that State, territory, or protectorate is in agreement and submits written documentation of such agreement as part of the application.

Note: Only one application per State, territory, or protectorate may be submitted.

Eligible laboratories may form consortia. Applications from consortia must provide documentation from each member of the consortium of their willingness to collaborate and pool data from each site in their proposed consortium. One laboratory of the consortium must be identified as the designated lead on a multi-site application. The lead laboratory must submit the application and administer the award.

For interested applicants, a telephone conference call for pre-application technical assistance will be held on Thursday, May 24, 2001, from 1:30 p.m. to 3:30 p.m., Eastern Standard Time. The bridge number for the conference call is 1–800–713–1971, and the pass code is 509361. For further information, please contact Charles Buxton at (770) 488–4160.

Note: Effective January 1, 1996, Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986, which engages in lobbying activities shall not be 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 2001 to fund approximately 25 awards. It is expected that the average award will be $200,000, ranging from $100,000 to $300,000. It is expected that the awards will begin on or about September 1, 2001, and will be made for a 12-month budget period within a project period of up to two years. Funding estimates may change.

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

Use of Funds

Funds may be used to develop a biomonitoring plan, to conduct surveys, hire consultants, hire and train personnel, conduct needs assessments and evaluations, conduct travel related to this project, pay for relevant and appropriate services, and perform other activities that enhance the recipient's ability to develop a biomonitoring program plan. Project funds may not be used for the development of testing methods or programs for environmental samples.

Funds may not be used to support activities which would otherwise be under the jurisdiction of Superfund and/or the Agency for Toxic Substances and Disease Registry. However, because toxicants from Superfund sites contribute to the total of human exposure sources, funds may be used for planning purposes to examine the interface between Superfund activities and public health laboratory biomonitoring programs.

Future Plans: CDC anticipates that during the second year of this grant program, a Cooperative Agreement program announcement will be issued with the intent to provide in FY 2003, the funding for approximately five public health laboratories at an anticipated level of $1,000,000 per laboratory, per year (for up to five years) to implement biomonitoring programs.

Eligibility for these Cooperative Agreement funds will be limited to those laboratories that have received funds under this grant program. Criteria for funding under the future Cooperative Agreement Program will include: the quality of the plan developed during this planning grant period; the degree to which the applicant demonstrates cooperation and integration with other public health resources (e.g., epidemiologists, schools of public health, medicine and science); and the assessment of the need for biomonitoring.

CDC anticipates that the awards during the Cooperative Agreement phase will be made with the goal of achieving geographic distribution and

balance among laboratories which serve people living in diverse settings such as urban, rural, agricultural, and industrial communities.

Funding Preferences

Preference for awards will be given to ensure geographic diversity.

D. Program Requirements

The program areas of interest focus on the development of a plan by which recipients will be able to achieve the following by the end of the two-year project period:

1. Assess the need for biomonitoring within the community served by the applicant. The laboratory should collaborate with other public health partners, including public health physicians and epidemiologists to make this needs assessment. Special consideration should be given to evaluating exposures in racial and ethnic population groups that may be at increased risk from exposure.

2. Develop a plan for implementing or expanding biomonitoring capacity in the public health laboratory. This plan should:

a. Define specific, measurable, and time-framed goals and objectives.

b. Inventory existing biomonitoring methods available to the applicant and specify for each method: toxic substance(s) measured, method of measurement (e.g., GC–MS, atomic absorption), current instrumentation used, the limit of detection for each analyte (and how the limit of detection was determined), known interferences, description of method's quality control, any external proficiency testing program in which the laboratory currently participates for the method, an approximate method sample throughput per day, and approximate number of human specimens analyzed in the past 12 months. (If an applicant is not currently performing biomonitoring testing, but anticipates this need, these needs should be stated as outlined in 2.c.)

c. Identify new biomonitoring capacity needed to address additional toxic substances or expand current methods. Emphasize in this section how the new biomonitoring capacity will be used to address needs identified in 1. As part of this explanation, specify the collaborations with public health partners (State and local health officials, schools of public health, academic centers, community groups, etc.) who will work with the lab to use biomonitoring data to help address these public health needs.

d. For each new biomonitoring method needed, describe additional requirements for personnel, instrumentation, and facilities modification or expansion. Provide cost estimates for facilities modification or expansion.

e. Describe requirements for local Institution Review Board (IRB) or Human Subjects review and approval.

f. Discuss requirements for compliance with the Clinical Laboratory Amendments (CLIA) 1988.

3. Develop an evaluation plan to assess progress in expanding the laboratory's biomonitoring capacity and to assess the impact of biomonitoring measurements on addressing the identified public health needs within the State or community.

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. Please follow the directions indicated in the application kit.

F. Submission and Deadline

Submit the original and five copies of PHS 398 (OMB Number 0925–0001) Forms are in the application kit.

On or before July 2, 2001, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the Objective Review Panel. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be reviewed, and will be returned to the applicant.

G. Evaluation Criteria

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

1. Understanding the Problem (30 Percent)

The extent to which the applicant understands the need for planning a biomonitoring program and the purpose of conducting exposure assessment by measurement of human biological samples (blood, hair, urine, saliva) to identify internal human dose from contact with hazardous environmental chemicals.

a. The analytical challenges associated with identifying extent of exposure based on data obtained from human samples, especially challenges presented by the differences in physiological makeup of individuals, specimen collection and pharmacokinetic and pharmacodynamic factors.

b. The problems related to estimating or extrapolating ''internal dose'' from ''external dose'' data, and the value of biomonitoring through direct measurement of samples from humans to provide more meaningful information.

2. Goals and Objectives (20 Percent)

The extent to which the applicant clearly states planning goals and objectives which are consistent with the Purpose and Program Requirements sections as presented in this announcement, and the degree to which the goals and objectives reflect an understanding of the need to reach beyond the laboratory to achieve balanced input from the broader public health community in preparing the biomonitoring plan.

3. Description of Program and Methodology (20 Percent)

Describe in detail how the biomonitoring plan will be developed, what sources of information and expertise will be utilized in establishing the plan. Describe a phased time line of activities leading to completion of the plan, and anticipated uses of the plan.

4. Collaborative Efforts (15 Percent)

Describe anticipated collaborative efforts related to this planning among the applicant laboratory, other components of the public health structure of the community, including epidemiologists, environmental health professionals, other state or local health agencies, health services providers, and academic institutions such as schools of public health, medicine, university departments of chemistry or biochemistry, community and citizens groups, and other interested parties. Letters of support from anticipated collaborators should be provided as attachments to the application package.

5. Evaluation Plan (10 Percent)

The extent to which the applicant describes how progress towards

achieving the applicant's goals and objectives will be evaluated, and how, once the plan has been completed, its impact on environmental health and human exposure issues in the applicant's community will be assessed.

6. Staffing, Management System, and Facilities (5 Percent)

The extent to which the applicant describes the staff available or anticipated to conduct the planning activities and how they will be managed. The applicant must describe the organizational setting and facilities available to support the development of the plan, to accumulate and analyze data and other information related to planning. Applicants should also describe planning to provide IRB review when biomonitoring programs are implemented and discuss the impact of the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) on their plan.

7. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

H. Other Requirements

Provide CDC with the original plus two copies of:

1. Annual progress reports, no more than 30 days after the end of the report period;
2. Financial status report, no more than 90 days after the end of the budget period;
3. Final financial report and performance report, no more than 90 days after the end of the project period; and
4. Completed planning document, no later than the end of the third quarter of year two.

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–7 Executive Order 12372 Review
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 sections 301 and 317 of the Public Health Service Act, 42 U.S.C. sections 241 and 247b, 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 home page Internet address—http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sonia V. Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, (MS E–13), Atlanta, GA 30341–4146, Telephone: (770) 488–2724, E-mail address: svp1@cdc.gov.

For program technical assistance contact: Dayton T. Miller, Ph.D., National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE (MS F–18), Atlanta, GA 30341–3724, Telephone: (770) 488–4452, E-mail address: dtm1@cdc.gov.

Dated: April 30, 2001.

John L. Williams,

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

[FR Doc. 01–11215 Filed 5–3–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Advisory Committee on HIV and STD Prevention: Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: CDC Advisory Committee on HIV and STD Prevention.

Times and Dates: 8:30 a.m.–5 p.m., June 4, 2001. Place: Holiday Inn, 130 Clairmont Ave, Decatur, Georgia 30030.

Place: 8:30 a.m.–5 p.m., June 5, 2001. Corporate Square Office Park, Corporate Square Boulevard, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This Committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

Matters to be Discussed: Agenda items include issues pertaining to (1) HIV prevention-care interface (2) HRSA–CDC linkages in terms of preventing STDs other than HIV (3) Syphilis elimination. Agenda items are subject to change as priorities dictate.

For Further Information Contact: Paulette Ford, Committee Management Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, Mailstop E–07, Atlanta, Georgia 30333. Telephone 404/639–8008, fax 404/639–3125, e-mail pbf7@cdc.gov.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 30, 2001.

John Burckhardt,

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

[FR Doc. 01–11218 Filed 5–3–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0185]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the