Consultation and Coordination With Indian Tribal Governments

ATSDR's mission is to prevent exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment.

ATSDR is committed to assisting tribal governments in meeting the environmental health needs of their people. ATSDR continues to work to improve its communication and cooperation with tribes. This new policy is in response to the Presidential Executive Order 13084, Consultation and Coordination With Indian Tribal Governments, May 14, 1998, and affirms the current ATSDR Policy on Government-to-Government Relations with Native American Tribal Governments (61 FR 42255). The policy focuses on environmental health issues related to the release of hazardous substances into the environment.

Consultations between ATSDR and tribal governments will continue to ensure effective collaboration in identifying, addressing, and satisfying the needs of tribal communities affected by hazardous substances. Consultation enables ATSDR staff and tribal members to interactively participate, exchange recommendations, and provide input on environmental health activities.

As defined by ATSDR, the new policy supports: (1) A consultative process with tribal nations and their members to work together to address tribal environmental public health needs; (2) mutual trust, respect, and shared responsibilities between all participating parties; and (3) open communication of information and opinions leading to mutual interaction and understanding.

ATSDR . . .

- Respects and honors the sovereignty of the tribes, the responsibilities and rights to self-governance, and the differences between tribal nations and individuals.
- Consults with tribal governments to ensure community concerns and impacts are carefully considered before the Agency takes action or makes decisions affecting tribal communities.
- Maintains government-to-government relationships with tribal governments.
- Ensures ongoing communication with tribal governments, communities, and individual tribal members to define concerns about possible health impacts from exposure to hazardous substances.

Dated: July 27, 1999.

Donna Garland,

Acting Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 99–19677 Filed 7–30–99; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00007]

Research on Laboratory Markers of Recent HIV Infection: Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of $500,000 of fiscal year (FY) 2000 funds for a cooperative agreement program for Research on Laboratory Markers for Recent HIV Infection. This program addresses the ''Healthy People 2000'' priority area of HIV Infection. The purpose of the Program is to support research on laboratory markers that can be used to measure HIV infection incidence from cross-sectional samples and identify recently infected persons.

One example of this approach is provided by a newly described testing algorithm using a modified enzyme immuno assay (EIA) for HIV–1 antibody to identify persons who are in the early period of HIV infection (Janssen et al, JAMA 1998; 280:42–48). Specimens that are positive for HIV antibody by a standard EIA and Western blot are retested with a less sensitive EIA. The method was developed using the Abbott 3A11 EIA as the standard assay and a modified Abbott 3A11 EIA (employing a more dilute specimen and shorter incubation time) as the less sensitive assay. Persons who are HIV-positive on the sensitive assay, but negative on the less sensitive assay, are considered to be recently infected.

The objective is to develop laboratory tests or algorithms for identifying recent HIV infection (e.g., 3–12 months). These might include modifying existing EIAs or developing new serologic assays or testing algorithms. These assays or algorithms should be of sufficient simplicity to permit routine use in public health surveillance and programs.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies: that is, universities, colleges, research institutions, hospitals, other public and private nonprofit, and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 104–65 specifies 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 $500,000 is available in FY 2000 to fund up to two (2) awards. It is expected that the average award will be $250,000. It is also expected that the awards will begin on or about January 2, 2000 and will be made for a 12-month budget period within a project period of up to two (2) 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.

Funding Preferences

Funding will be awarded to applicants proposing different approaches, in order to avoid funding more than one laboratory for the same or very similar research.

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 activities under 2. (CDC Activities).

1. Recipient Activities

a. Develop an innovative testing methodology for identifying recent HIV infection, or adapt another commercially available HIV–1 serum EIA to detect early HIV–1 infection in individuals (e.g., 3–12 months), or adapt such methods to other body fluids (oral fluids, urine, etc.), or adapt such methods to rapid HIV testing.

b. Validate methods in appropriate study populations or appropriate panels of specimens using appropriate statistical methods for analysis.

c. Provide results and share data (individual & aggregate) with other collaborators in the field and with CDC.

2. CDC Activities

a. If the research protocol involves human subjects, CDC will assist in the development of a research protocol for

Institutional Review Board (IRB) review by each cooperating institution participating in the research project.

The CDC Institutional Review Board (IRB) will review and approve the protocol initially and on at least an annual basis until the research project is completed.

b. Provide assistance in the design and conduct of the research and statistical analysis.

c. Provide assistance on selected laboratory tests, when requested.

d. Coordinate research activities among diverse sites, when appropriate, as there may be identical samples that require testing by more than one venue.

e. Assist in the analysis of research information and the presentation and publication of research findings.

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 ten (10) double-spaced pages, printed on one side, with one inch margins, and unreduced font.

Budget

1. Submit line-item descriptive justification for personnel, travel, supplies, and other services. Be precise about the purpose of each budget item as it relates to the project.

2. If you request funding for contracts, include the name of the person or firm to receive the contract, the method of selection, the period of performance, the reason for using a contract, and a description of the contracted service requested.

3. Funding levels for year two (2) should be estimated.

Supporting Materials

1. Curriculum vitae and job description of critical staff.

2. Letters of endorsement or collaboration of participating centers, agencies or State or local public health departments.

F. Submission and Deadline

Application

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189). Forms are available at the following internet address: www.CDC.gov...forms or in the application kit. On or before October 4, 1999, 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 independent review group. (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 criteria in (a) or (b) above are considered late applications, will not be considered, 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. The applicant demonstrates the knowledge, ability, and experience necessary to conduct laboratory research on measures of recent HIV infection. (20 points)

2. The applicant demonstrates the ability to obtain and examine appropriate numbers and types of laboratory specimens. (20 points)

3. The applicant presents a sound plan for conducting and evaluating the research, including appropriate statistical analysis. (20 points)

4. The applicant's proposed objectives are measurable, specific, time-phased, and related to required recipient activities and program purpose. (20 points)

5. The applicant demonstrates willingness to cooperate in a study with CDC and other collaborating institutions. (10 points)

6. The size, qualifications, and other time allocation of the proposed staff and the availability of facilities are adequate for the study. (10 points)

7. The budget is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized. (not scored)

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

9. 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; and (c) A statement as to whether the design of the study is adequate to measure differences when warranted. (not scored)

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress Reports (semi annual);

2. Financial Status Report (FSR), no more than 90 days after the end of the budget period; and

3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Van Malone, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341.

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–4 HIV/AIDS Confidentiality Provisions
AR–5 HIV Program Review Panel Requirements
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Section 301 of the Public Health Service Act, [42 U.S.C. 241, Section 311, 42 U.S.C. 243], as amended. The Catalog of Federal Domestic Assistance number is 93.943.

J. Where To Obtain Additional Information

Please refer to Program Announcement 00007 when you request information. For a complete program description, information on application procedures, an application package, and business management technical assistance, contact: Van Malone, Grants Management Specialist, Procurement and Grants Office, Announcement

00007, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341, Telephone: (770) 488–2733, Email address: Vxm7@cdc.gov.

For program technical assistance, contact: Donald Ruberti, Senior Public Health Advisor, Prevention Services Research Branch, Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mail Stop E46, Atlanta, Georgia 30333, Telephone: (404) 639–2098, Email address: http://www.dor1@cdc.gov. See also the CDC Home Page on the Internet: http://www.cdc.gov

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.

Dated: July 27, 1999.

John L. Williams,

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

[FR Doc. 99–19675 Filed 7–30–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0926]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Regulations Under the Federal Import Milk Act; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 26, 1999 (64 FR 40379). The document announced that a proposed collection of information has been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The document was published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 99–18927, appearing on page 40379 in the **Federal Register** of Monday, July 26, 1999, the following corrections are made:

1. On page 40379, in the first column, the Docket number is corrected to read ''99N–0926''; and in the second column, under the **SUPPLEMENTARY INFORMATION** caption, in the title of the proposed collection of information, the OMB control number ''0910–021'' is corrected to read ''0910–0212''.

Dated: July 27, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation

[FR Doc. 99–19688 Filed 7–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

International Workshop on the Standardization of Whole Blood Coagulation Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a workshop entitled ''International Workshop on the Standardization of Whole Blood Coagulation Devices.'' The focus of the workshop is to define the issues relating to the calibration of whole blood coagulation assays. Workshop participants will be asked to develop a proposal for standardizing the calibration of these devices. The proposal will be referred to a standards development organization.

DATE: The workshop will be held on August 13, 1999, 1 p.m. to 6 p.m.

ADDRESSES: The workshop will be held at the Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Sheila J. Murdock, Office of Surveillance and Biometrics (HFZ–510), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3060, FAX 301–594–2968, e-mail ''coagulation@cdrh.fda.gov''.

SUPPLEMENTARY INFORMATION: Whole blood clotting assays are used increasingly in the point of care testing environment. The calibration of these assays against plasma methods is achieved through a variety of approaches. Consequently, the consistency of results between different devices and the traceability of results to plasma methods are variable. Limited correlation between assays can be particularly problematic when monitoring anticoagulant drugs.

The workshop will focus on defining the issues relating to the calibration of whole blood coagulation devices. Workshop participants will collaborate on a proposal for the development of a standardized approach to the calibration of these assays. The proposal will be referred to a standards development organization.

In order to make the best use of limited workshop time, guest speakers will be asked to write a draft standardization proposal prior to the date of the workshop. This document will be posted on the CDRH website after July 15, 1999, at ''http://www.fda.gov/cdrh/meetings/coag.html''. Members of the public will be encouraged to e-mail comments and recommendations about this document to ''coagulation@cdrh.fda.gov''. Summaries of all e-mailed comments sent with author's name will be posted to the website in order to provide a forum for ongoing discussion up to the week of the workshop.

Those persons interested in attending the workshop should fax or e-mail their registration including name, title, affiliation (i.e., end-user, government nonregulatory, government regulatory, industry, professional organization, proficiency testing organization, trade press, standards development organization), mailing address, telephone number, fax number, e-mail address, and area of interest. There is no charge to attend the workshop, however, advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Shirley L. Meeks at least 7 days in advance of the meeting, at the Office of Systems Management (HFZ–17), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1283, ext. 105, FAX 301–827–2929, e-mail ''SLM@CRDH.FDA.GOV''.

Registration forms and the preliminary agenda may also be accessed at the CDRH website at ''http://www.fda.gov/cdrh/meetings/coag.html''. The workshop agenda includes presentations by guest speakers, small breakout group discussions and deliberation and refining of a standardization proposal. The final plenary session will include reports to the assembly from the smaller group discussions. Time will be provided for public comments at the end of this session. The draft standardization proposal will be finalized according to the