For program technical assistance, contact: Paul A. Rota, Ph.D., Supervisory Microbiologist, National Center for Infectious Diseases, Centers for Disease Control and Prevention, MS–C–22, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone: (404) 639–4181, E-mail: *Prota@cdc.gov.*

Dated: May 1, 2003.

Edward Schultz,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03057]

Cooperative Agreement for a National Poison Prevention and Control Program; Notice of Availability of Funds

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a), 317(k)(2), 391, 392, and 394A [42 U.S.C. 241(a), 247b(k)(2), 280b, 280b-1, 280b-3] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.136.

B. Purpose

The Centers for Disease Control and Prevention (CDC) and Health Resources Services Administration (HRSA) announce the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for a National Poison Prevention and Control Program. This program addresses the ''Healthy People 2010'' focus area of Injury and Violence Prevention.

The purpose of the program is to support an integrated system of poison prevention and control services including the following: Completing implementation of and maintaining the nationwide toll-free number for poison control services; developing, implementing, and evaluating prevention and public awareness activities associated with the toll-free number; and sustaining improvements to the national Toxic Exposure Surveillance System (TESS).

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the NCIPC: (1) Increase the capacity of injury prevention and control programs to address the prevention of injuries and violence; (2) monitor and detect fatal and non-fatal injuries; and (3) conduct a targeted program of research to reduce injury-related death and disability.

C. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations, faith-based and community-based organizations, and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and Federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

D. Funding

Availability of Funds

Up to $3,900,000 of FY 2003 funds are available to fund one award. It is expected that the award will begin on or about September 14, 2003, 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.

Recipient Financial Participation

Matching funds are not required for this program.

E. Program Requirements

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

1. Recipient Activities

(a) Develop a plan to improve the current national toxicosurveillance system, with a focus on improvement of data collection and coding at a select sample of poison control centers.

(b) Implement and maintain the nationwide toll-free telephone number for poison control services.

(c) Develop and implement a national public service media campaign to familiarize health care professionals, public health professionals, and the public with poison control services. Establish a media campaign stakeholder committee, comprised of poison control center health educators, state health department injury prevention professionals, and representatives from relevant national organizations, to guide this effort.

(d) Promote broad use of the toll-free number by poison control centers, professionals, and the public by using materials developed by the American Association of Poison Control Centers (AAPCC) in 2002.

(e) Conduct an independent evaluation of materials developed in 2002, such as English- or Spanish-language promotional brochures or preschool education materials. Use formative research methods to test effectiveness in target audiences

(f) Respond to the request for interim reports to assure progress on the objectives of the cooperative agreement is being made; and meet, semiannually, with CDC and HRSA staff to identify and address problems.

2. CDC Activities

(a) Provide coordination between the grantee and HRSA, on all aspects of recipient activities.

(b) Collaborate in the evaluation of the improvements of data collection at a sample of poison control centers.

(c) Evaluate coding at a select sample of poison control centers.

(d) Provide technical assistance for the effective planning and management of the development and implementation of the public service media campaign.

(e) Serve, with HRSA staff, as ex-officio members of the media campaign stakeholder committee.

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 developing your program plan. The narrative should be no more than 30 double-spaced pages, printed on one side, with one-inch margins, and unreduced 12-point font.

The narrative should consist of:

1. *Abstract:* A one page abstract and summary of the proposed effort.

2. *Background and Need:* Application should describe the background and need for an integrated program of poison prevention and control services including the following: Maintaining the nationwide toll-free number for

poison control services; developing, implementing, and evaluating prevention and public awareness activities associated with the toll-free number; and sustaining improvements to the national Toxic Exposure Surveillance System (TESS).

3. *Methods:* Describe activities required to implement an integrated system of poison prevention and control services, as mentioned in the purpose section of this announcement. Provide (a) goals and objectives for implementation, and (b) a two-year timeline for implementation of activities that is logically sequenced. Describe the coordination of the poison control centers and other organizations that will participate and how this will occur. Include letters of support from all involved individuals and organizations.

Describe how you have addressed 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.

(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.

4. *Objectives:* Describe long- and short-term objectives that are specific, measurable, attainable, and realistic. Process and outcome objectives should be designed to accomplish all activities of the program during the project period.

5. *Evaluation:* Design an evaluation to document program process and effectiveness in achieving objectives to deliver poison prevention and control services. Document staff availability, expertise, and capacity to perform this evaluation.

6. *Staff and Resources:* Describe the responsibilities of the program coordinator and each of the other staff members responsible for carrying out the program, including experience, professional education, and time devoted to the program. A curriculum vita should be included for each critical staff member.

7. *Budget:* Include a detailed budget with accompanying narrative justifying all individual budget items that make up the total amount of funds requested. The budget should be consistent with the stated goals and objectives.

8. *Performance Goals:* Describe 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.

G. Submission and Deadline

Application Forms

Submit the signed original and two copies of PHS 5161–1 (OMB Number 0920–0428). Forms are available at the following Internet address: *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 23, 2003. Submit the application to: Technical Information Management—PA#03057, 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:

1. Background and Need (25 percent). The extent to which the applicant presents an understanding of the need for a national poison prevention and control program and demonstrates experience in this area, especially the ability to work with poison control centers and their key issues, and describes the likely impact of their activities on this problem.

2. Staff and Resources (25 percent). The extent to which the applicant can provide adequate facilities, staff and/or collaborators, including a full-time coordinator and resources to accomplish the proposed goals and objectives during the project period. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, previous experience, and capacity to perform the undertaking successfully.

3. Methods (20 percent). The extent to which the applicant provides a detailed description of all proposed activities and collaboration needed to achieve each objective and the overall program goal(s). The extent to which the applicant provides a reasonable logically sequenced and complete schedule for implementing all activities. The extent to which position descriptions, lines of command, and collaborations are appropriate to accomplishing the program goal(s) and objectives.

The extent that the application adequately addresses 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.

(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.

4. Objectives (10 percent). The extent to which the applicant describes long and short term objectives that are specific, measurable, attainable, and realistic. The extent to which objectives are time-framed process and outcome objectives designed to accomplish all activities of the program.

5. Evaluation (10 percent). The extent to which the proposed evaluation plan is detailed and capable of documenting program process and outcome measures. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, and capacity to perform the evaluation.

6. Performance Goals (10 percent). The extent to which the applicant provides 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.

7. Budget and Justification (Not Scored). The extent to which the applicant provides a detailed budget and narrative justification consistent with the stated objectives and planned program activities.

8. Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress report, by April 15th. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

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

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.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement, as posted on the CDC Web site.

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–13—Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR–14—Accounting System Requirements
AR–15—Proof of Non-Profit Status

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general 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 business management and budget assistance, contact: Nancy Pillar, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2721, E-mail address: *nfp6@cdc.gov*.

For program technical assistance, contact: Stacy L. Harper, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway NE., Mailstop F41, Atlanta, GA 30341–3724, Telephone: 770–488–4031, E-mail address: *SLHarper@cdc.gov*.

Dated: May 1, 2003.

Edward Schultz,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E–0064]

Determination of Regulatory Review Period for Purposes of Patent Extension; TRACLEER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TRACLEER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical