I. Authority and Catalog of Federal Domestic Assistance Number

This program announcement is authorized under Sections 391, 392, 393, and 394 [42 U.S.C. 280b, 280b–1, 280b–1a, and 280b–2] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

The program announcement and application forms may be downloaded from the Internet: www.cdc.gov (look under funding). You may also receive a complete application kit by calling 1–888–GRANTS4. You will be asked to identify the program announcement number and provide your name and mailing address. A complete announcement kit will be mailed to you.

Please refer to Program Announcement 98071 when you request information.

If you have questions after reviewing the forms, for business management technical assistance, contact: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98071, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305–2209, telephone (404) 842–6535, E-mail address jcw6@cdc.gov.

For program technical assistance, contact Wendy Watkins, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–60, Atlanta, Georgia 30341–3724, telephone (770) 488–4646, E-mail address dmw7@cdc.gov.

Dated: June 5, 1998.

John L. Williams,

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

[FR Doc. 98–15545 Filed 6–10–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 98072]

The Evaluation of Interventions to Prevent Suicide

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program for the Evaluation of Interventions to Prevent Suicide. This program addresses the ''Healthy People 2000'' priority area Violent and Abusive Behavior.

The purpose of this cooperative agreement is to evaluate specific interventions that may influence one or more of the factors that lead to suicidal behavior among high-risk populations (see Addendum II—Background for additional information included in the application kit).

B. Eligible Applicants

Applications may be submitted by public and private nonprofit 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.

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 $400,000 is available in fiscal year 1998 to fund up to two awards. It is expected that projects completed in three years will have an average award of $200,000 and ranging from $175,000 to $225,000 per year. Awards will be made for a 12 month budget period within a three year project period.

Non-competing continuation awards for new budget periods within an approved project period are made on the basis of satisfactory performance and availability of funds.

Funding Preferences

In making awards, priority consideration will be given to ensuring a balance among types of interventions (e.g., peer support, gatekeeper training) and programs that target different high-risk populations (e.g., age groups, sex, race/ethnicity).

D. Cooperative Activities

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under 1., below, and CDC shall be responsible for the activities under 2., below:

1. Recipient Activities:

a. Develop a protocol for evaluating the specific intervention.

b. Develop procedures for collecting and compiling information relevant to the proposed project.

c. Develop and pilot test instruments for data collection.

d. Establish goals and realistic, measurable, time-oriented objectives.

e. Develop, implement, and evaluate the selected intervention.

f. Compile and disseminate the results from the project.

2. CDC Activities:

a. Provide technical assistance in defining the target population.

b. Collaborate in the design of all phases of the evaluation.

c. Provide technical assistance in sharing information among the various evaluation projects awarded.

d. Provide up-to-date scientific information about suicidal behavior prevention.

e. Assist in the transfer of information and methods developed in these projects to other prevention programs.

E. Application Content

Use the information in the Cooperative Activities, Other Requirements, Evaluation Criteria sections and the Errata Sheet (Addendum III), included in the application package 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 30 double-spaced pages, printed on one side, with one inch margins, and unreduced font (no smaller than 10 cpi).

F. Submission and Deadline

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) and adhere to the instructions on the Errata Instruction Sheet for PHS 398. Forms are in the application kit.

On or before August 4, 1998, submit to: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98072, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305–2209.

If your application does not arrive in time for submission to the independent review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

G. Evaluation Criteria

Each application will be evaluated individually against the following

criteria by an independent review group appointed by CDC.

Applicants will be evaluated according to the following criteria (Maximum of 100 total points):

1. Intervention Plan (35 Points)

a. Target Group

The extent to which the target group is described and access to the target population is demonstrated. The extent to which the target group has a high incidence or prevalence of the risk factors to be influenced by the proposed intervention and the extent to which appropriate demographic and morbidity data are described. The extent to which youth, who are the direct or indirect target group, have a high incidence of interpersonal violence and violence-related injuries, disabilities, and deaths. The extent to which the applicant demonstrates a capability to achieve a sufficient level of participation by the target group in order to evaluate the intervention in an unbiased fashion. In addition, the degree to which the applicant has met the CDC/ATSDR policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. This includes:

i. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

ii. The proposed justification when representation is limited or absent.

iii. A statement as to whether the design of the evaluation is adequate to measure differences when warranted.

iv. A statement as to whether the plans for recruitment and outreach for intervention participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

b. Intervention Description

The extent to which the potential effectiveness of the intervention is theoretically justified and supported by epidemiologic, or social and behavioral research. The extent to which the intervention is feasible and can be expected to produce the expected results in the target group of interest. The extent to which the intervention, its implementation, the development of all necessary materials, and all necessary training are clearly described. The extent to which the desired outcomes are specified and definitions of measurable endpoints are provided (e.g., behavioral change, injury, disability, or death). The extent to which the setting in which the intervention is to be implemented is clearly described and shown to be adequate for reaching the target group and achieving the desired objectives. The status of all necessary measurement instruments or training materials must be described; if any of this material is not extant, methods and time frames for their development must be described. Necessary collaborators must be identified, and evidence of their ability and intention to participate must be supplied. The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable.

2. Evaluation Design and Analysis (35 Points)

The extent to which the evaluation design and the data analysis plan are clearly described and are appropriate for the target group, intervention, data collection opportunities, and proposed project period. The extent to which the various threats to the validity of the evaluation are recognized and addressed. The extent to which the sampling methods, sample size estimates, power estimates, and attrition of the participating population are clarified. The extent to which data collection, data processing, and management activities are clearly described. The extent to which the major phases of the project are clearly presented and logically and realistically sequenced. The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable.

3. Project Management and Staffing Plan (10 Points)

The extent to which project management staff and their working partners are clearly described, appropriately assigned, and possess pertinent skills and experiences to conduct the project successfully to completion. The extent to which the applicant has arranged to involve appropriate researchers and other personnel who reflect the racial/ethnic composition of the target group. The extent to which the applicant or a full working partner demonstrates the capacity and facilities to design, implement, and evaluate the proposed intervention.

4. Collaboration (20 Points)

The extent to which the necessary partners are clearly described and their qualifications and intentions to participate explicitly stated. The extent to which the applicant provides proof of support (e.g., letters of support and/or memoranda of understanding) for proposed activities. The extent to which a full working partnership between a community-based organization, a university or other academic institution, and a State or local health department has been established for applicants seeking funds for a three year project period. Evidence must be provided that these funds do not duplicate already funded components of ongoing projects.

5. Human Subjects (Not Scored)

If human subjects will be involved, how they will be protected, i.e., describe the review process which will govern their participation.

6. Proposed Budget (Not Scored)

The extent to which the budget request is clearly explained, adequately justified, reasonable, sufficient for the proposed project activities, and consistent with the intended use of the cooperative agreement funds. Budgets should include costs for travel for two project staff to attend two meetings per year in Atlanta with CDC staff.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports.

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

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

Confidentiality of Records

All identifying information obtained in connection with the provision of services to any person in any program that is being carried out with a cooperative agreement made under this announcement shall not be disclosed unless required by a law of a State or political subdivision unless written, voluntary informed consent is provided by persons who received services.

1. Nonpersonal identifying, unlinked information, which preserves the individual's anonymity, derived from any such program may be disclosed without consent:

a. In summary, statistical, or other similar form, or

b. For clinical or research purposes.

2. Personal identifying information: Recipients of CDC funds who must obtain and retain personal identifying information as part of their CDC-approved work plan must:

a. Maintain the physical security of such records and information at all times;

b. Have procedures in place and staff trained to prevent unauthorized disclosure of client-identifying information;

c. Obtain informed client consent by explaining the risks of disclosure and the recipient's policies and procedures for preventing unauthorized disclosure;

d. Provide written assurance to this effect including copies of relevant policies; and

e. Obtain assurances of confidentiality by agencies to which referrals are made.

Assurance of compliance with these and other processes to protect the confidentiality of information will be required of all recipients. A Department of Health and Human Services (DHHS) certificate of confidentiality may be required for some projects.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum I (included in the application kit).

AR98–1 Human Subjects Requirements
AR98–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR98–9 Paperwork Reduction Act Requirements
AR98–10 Smoke-Free Workplace Requirements
AR98–11 Healthy People 2000
AR98–12 Lobbying Restrictions
AR98–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

Send all reports to: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305–2209.

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For program technical assistance, contact Tim Thornton, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–60, Atlanta, GA 30341–3724, telephone, (770) 488–4646, E-mail address, tnt1@cdc.gov.

Dated: June 5, 1998.

John L. Williams,

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

[FR Doc. 98–15541 Filed 6–10–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0003]

Dulal C. Chatterji; Grant of Special Termination; Final Order Terminating Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) granting special termination of the debarment of Dr. Dulal C. Chatterji, 308 Dalton Dr., Raleigh, NC 27615. FDA bases this order on a finding that Dr. Chatterji provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction, and that special termination of Dr. Chatterji's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

EFFECTIVE DATE: JUNE 11, 1998.

ADDRESSES: Comments should reference Docket No. 96N–0003 and be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

In a **Federal Register** notice dated January 22, 1997 (62 FR 3297), Dr. Dulal C. Chatterji, cofounder, part owner, vice-president for scientific affairs, and head of the research and development (R&D) division at the generic drug manufacturer Quad Pharmaceuticals, Inc. (Quad), was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 306(c)(1)(B) and (c)(2)(A)(ii)) and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 321(dd)). The effective date of the debarment was November 1, 1995, based on Dr. Chatterji's acquiescence to debarment. The debarment was based on FDA's finding that Dr. Chatterji was convicted of a felony under Federal law for conduct relating to the development or approval of any drug product, or otherwise relating to the regulation of a drug product under section 306 of the act. On April 7, 1997, Dr. Chatterji applied for special termination of debarment under section 306(d)(4) of the act, as amended by the Generic Drug Enforcement Act.

Under section 306(d)(4)(C) and (d)(4)(D) of the act, FDA may limit the period of debarment of a permanently debarred individual if the agency finds that the debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in paragraph (a) or (b) of section 306 of the act or relating to a matter under FDA's jurisdiction. If substantial assistance is found, the extent to which debarment may be terminated will depend upon the agency's assessment of whether termination will serve the interest of justice and not threaten the integrity of the drug approval process. Special termination of debarment is discretionary with FDA.

FDA considers a determination by the Department of Justice that an individual provided substantial assistance conclusive in most cases. Dr. Chatterji fully cooperated with the Department of Justice investigations and prosecutions of others within Quad for offenses related to matters under FDA jurisdiction, as substantiated by two letters received by FDA from the U.S. Attorney's Office for the District of Maryland. Accordingly, FDA finds that Dr. Chatterji provided substantial assistance as described under section 306(d)(4)(C) of the act.