## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Program Announcement 02002]**

### Grants for Rape Prevention and Education; Notice of Availability of Funds

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for grants to state and territorial health departments, to support programs addressing violence against women. The Rape Prevention and Education Grant Program strengthens violence against women prevention efforts by supporting increased awareness, education and training, and the operation of hotlines. The purpose of this program is to award formula grants to States and Territories to be used for rape prevention and education programs conducted by rape crisis centers, State sexual assault coalitions, and other public and private nonprofit entities. This announcement addresses the ''Healthy People 2010'' focus areas of injury and violence prevention.

#### B. Eligible Applicants

Assistance will be provided only to the health departments of States and territories, or their bona fide agents who are current recipients of Rape Prevention and Education funding, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

#### C. Availability of Funds

Approximately $42,000,000 is available in FY 2002, for funding under this formula based grant program (refer to attachment 1 in the application kit). It is expected that the awards will be made on two cycles. The first cycle will begin on or about January 1, 2002, and the second cycle will begin on or about June 1, 2002. The awards will be made for a 12-month budget period within a project period of up to five years.

The funding formula is based on population. The population used for the States, the District of Columbia, and Puerto Rico is based on the Census conducted April 1, 2000. This information is available at www.census.gov/population/www/cen2000/respop.html. The population used for the remaining territories is based on the U.S. Census International Data Base dated May 10, 2000. This information can be accessed at (www.census.gov/ipc/www/idbsum.html). 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 availability of funds.

*Use of Funds*

Pre-award cost is authorized up to three months before the effective date of the award.

Funds will be used for Rape Prevention and Education Programs specifically to conduct:

1. Educational seminars;
2. The operation of hotlines;
3. Training programs for professionals;
4. The preparation of informational material;
5. Training programs for students and campus personnel designed to reduce the incidence of sexual assault at colleges and universities;
6. Education to increase awareness about drugs used to facilitate rapes or sexual assault; and
7. Other efforts to increase awareness of the facts about, or to help prevent sexual assault, including efforts to increase awareness in under-served communities and awareness among individuals with disabilities (as defined in section 3 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12102)).

Applicants must adhere to Congressional legislation (section 393B of the Public Health Service Act (42 U.S.C. 280b *et seq.*)).

The Legislation stipulates the following:

1. Applicants may not use more than five percent of the amount received for each fiscal year (exclusive of Direct Assistance) for administrative expenses. This five percent limitation is in lieu of, and replaces, the indirect cost rate.
2. An applicant may not use more than two percent of the amount received for each fiscal year for surveillance studies or prevalence studies.
3. Amounts provided to applicants must be used to supplement, and not supplant Preventive Health and Health Services Block Grant, other Federal, State, and local public funds expended to provide the services described above.
4. Grant funds cannot be used for construction, renovation, the lease/purchase of passenger vehicles or the development of major software applications.

#### D. Application Content

Applications may be submitted electronically using the Rape Prevention and Education Grant System (RPEGS) format. The RPEGS application will include the following:

1. Executive Summary;
2. Program Narrative including goals and objectives;
3. Budget and Justification; and
4. Cost Allocations for Surveillance and Core RPE activities.

All eligible applicants will receive the RPEGS software no later than September 4, 2001. CDC will provide technical and administrative support to ensure the timely submission of applications. To provide technical assistance for this RFA, CDC will conduct pre-application conference calls with PA 02002 eligible applicants on August 27, 2001 and September 5, 2001. Details are as follows:

To provide technical assistance for this RFA, CDC will conduct pre-application calls with PA 02002 recipients on August 27, 2001 and September 5, 2001. Details are as follows:

1. Date: August 27, 2001 (Monday)
Time: 2:00 PM–4:00 PM (EST)
Telephone: USA Toll Free Number: (888) 394–4822; USA Toll Number: (712) 257–3329
PASSCODE: CDC RPE CONF
Conference Host: Neil Rainford

2. Date: September 5, 2001 (Wednesday)
Time: 2:00 PM–4:00 PM (EST)
Telephone: USA Toll Free Number (800) 713–1971; USA Toll Number (404) 639–4100
Conference Code: 585112

#### F. Submission and Deadline

*Application*

Submit the original copy and two copies of PHS form 5161–1, (OMB Number 0937–0189). Forms are located in the RPEGS certifications section. Forms are also available at: www.forms.psc.gov

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

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

(b) Postmarked on or before the deadline dates and received in time for orderly processing.

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

*Application Due Dates*

*Cycle A:* November 1, 2001. For States and Territories that require FY 2002

RPE funds prior to February 28, 2002. Award Date: January 1, 2002.

*Cycle B:* April 1, 2002. For all other States and Territories. Award Date: June 1, 2002.

**G. Human Subjects**

a. The applicant should describe the degree to which human subjects may be at risk and what protections will be in place to assure protection and confidentiality.

b. The applicant should demonstrate that it has adequately addressed the requirements of Title 45 CFR Part 46 for the protection of human subjects.

**H. Other Requirements**

*Technical Reporting Requirements*

1. a progress report shall be submitted annually, no later than 90 days after the end of each budget period.

2. a financial status report shall be submitted, no later than 90 days after the end of each budget period.

3. a final financial status report shall be submitted, no later than 90 days after the end of the five year project period.

The following additional requirements are applicable to this program. For a complete description of each see Addendum 1.

AR–1 Human Subjects Requirements
AR–7 Executive Order 12372 Review
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–22 Research Integrity

**I. Authority and Catalog of Federal Domestic Assistance Number**

In addition to being authorized under 301 (a) (42 U.S.C. 241(a)) of the Public Health Service Act, this program announcement is also authorized under 391 (a) and 393B (42 U.S.C. 280(b) et seq) of the Public Health Service Act. The catalog of Federal Domestic Assistance number is 93.136.

**J. Where To Obtain Additional Information**

This and other CDC announcements can be found on the CDC homepage on the Internet http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:Sheryl Heard, Grants Management Specialist,Grants Management Branch,Procurement and Grants Office,Program Announcement 02002,Centers for Disease Control and Prevention (CDC) 2920 Brandywine Road, Room 3000 Atlanta, Georgia 30341 Telephone: (770) 488–2723 Email address: slh3@cdc.gov

For program technical assistance, contact:Wendy Watkins, Program Manager,Division of Violence Prevention,National Center for Injury Prevention and Control,Centers for Disease Control and Prevention (CDC) 4770 Buford Highway, NE, Mailstop K–58 Atlanta, GA 30341–3724 Telephone: (770) 488–1567 Email address: dmw7@cdc.gov.

Dated: August 13, 2001.

**John L. Williams,**

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

[FR Doc. 01–20753 Filed 8–16–01; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0174]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; FDA Recall Regulations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by September 17, 2001.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**FDA Recall Regulations—Part 7 (21 CFR Part 7 (Subpart C))—(OMB Control Number 0910–0249)—Extension**

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7, subpart C sets forth the recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA-regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluating return reply cards, effectiveness checks, and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2000. The resulting number of recalls from this database search (1,933) is used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the above information to be 157,675 burden hours.

In the **Federal Register** of May 1, 2001 (66 FR 21767), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received on the information collection.

We agree with the comment that the agency is slow in providing the recall classification letter to recalling firms and are taking steps to streamline the classification process which, in turn, will improve the timeliness of the classification letter. However, we