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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00109]

Cooperative Agreements for National Programs That Build the Capacity of Schools To Prevent Foodborne Illness Through Coordinated School Food Safety Programs; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for cooperative agreements that establish a national program to assist the nation's schools and health departments to prevent foodborne illness through coordinated school food safety programs.

The purpose of this announcement is to develop a national program that builds the capacity of national non-governmental, non-profit organizations' constituents to help schools prevent foodborne illness. CDC recognizes that many state education agencies (SEAs) and local education agencies (LEAs) have implemented components of a coordinated school health program that addresses important health risk behaviors and health problems. This announcement provides support to national non-governmental, non-profit organizations to collaborate with state education agencies, state health agencies and others engaged in activities related to Coordinated School Health Programs to focus on foodborne illness prevention and school food safety.

CDC is committed to working collaboratively with the nation's state education and health agencies and to helping them implement comprehensive school health education as part of a coordinated school health program that can prevent the leading causes of death and disability. CDC is also committed to achieving the health promotion and

disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus area(s) of Educational and Community-Based Programs. For the conference copy of "Healthy People 2010", visit the internet site: <http://www.health.gov/healthypeople>.

B. Eligible Applicants

Assistance will be provided only to national organizations that are private health, education, or social service agencies (professional, or voluntary); and must qualify as a non-profit 501 (c)(3) entity. Priority will be given to organizations whose constituencies have a direct impact on the school food safety program including school food service professionals, school nurses, and administrators. Eligible applicants must have the capacity and experience to assist their local affiliates. Applicants and their local affiliates must have experience working with personnel from state and local education agencies, state or local health agencies, or other relevant agencies within the previous ten years that could contribute toward foodborne illness prevention efforts through coordinated school food safety programs. Eligible organizations must have affiliate offices or local/state/or regional membership constituencies in a minimum of 10 states and territories. Affiliate offices and local/state/or regional membership constituencies may not apply in lieu of, or on behalf of, their parent national office.

National organizations that are funded currently by CDC/Division of Adolescent and School Health (DASH) under program announcements 99023, and 97065, 00026, or 00037 are not eligible for this program announcement. A listing of CDC/DASH funded national organizations that are not eligible to apply is provided on the DASH website, <http://www.cdc.gov/nccdphp/dash/>.

Note: Public Law 104-65 states 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 \$420,000 is available in FY 2000 to fund approximately three awards. It is expected that the average award will be \$140,000, ranging from \$125,000 to \$155,000 and that the project period will be for 3 years. It is expected that the awards will begin on or about September 30, 2000. 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.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under section 1 (Recipient Activities), and CDC will be responsible for conducting activities under section 2 (CDC Activities) as listed below:

1. Recipient Activities

a. Collaborate with constituents; state and local education, health, agriculture, and social service agencies; non-governmental partners; and federal government agencies to develop a national strategy to prevent foodborne illness within school-based food safety programs.

b. Establish specific, measurable, and realistic goals and objectives that reduce and/or manage school foodborne illness outbreaks.

c. Establish an operational plan that includes collaborating with federal and state agencies and others engaged in coordinated school food safety program-related activities, in developing target-audience and discipline-specific training materials needed to effectively build the capacity of school personnel to implement a model coordinated school food safety program.

d. Specific activities can also include:

1. Build the capacity of constituents to better prevent school foodborne illness and implement a model coordinated school food safety program through participation in 3-4 training workshops facilitated by a State Education Agency;

2. Develop discipline-specific training materials for accompanying a model coordinated school food safety program for constituents;

3. Evaluate the effectiveness of the program in achieving goals and objectives;

4. Disseminate programmatic information through appropriate methods, such as:

a. Sharing materials that would reduce school foodborne illness through a variety of mechanisms (e.g. clearinghouses, conferences and/or workshops, newsletters, annual progress reports, etc.).

b. Sharing project-related news and information with State and Local Education Agencies, State Health Agencies, national organizations, and others through the Internet, other computer networks, the mail and at workshops and conferences;

5. Help schools, or other agencies that serve young people, conduct coordinated programs that prevent behaviors that place elementary through college-aged young people at risk for foodborne illness;

6. Collaborate with other national organizations to establish and maintain initiatives to prevent behaviors that place elementary through college-aged young people at risk for foodborne illness;

7. Educate and enable managers, leaders, teachers, school food service managers, school nurses, and decision makers who are members of the national organizations to act individually and collectively to support locally determined programs to reduce/manage school foodborne illness outbreaks;

8. Educate and enable families, media, businesses, and others in the community to act individually and collectively to support coordinated school health programs to reduce/manage school foodborne illness outbreaks;

9. Build the capacity of community agencies and parents to establish and/or maintain programs that reduce/manage school foodborne illness outbreaks;

10. Provide technical assistance and training to professionals and parents to use proven, effective strategies and programs to prevent behaviors that place elementary through college-aged young people at risk for foodborne illness.

11. Participate in national conferences to promote model coordinated school food safety programs.

12. Participate in CDC-planned meetings of national, state, and local education agencies and other appropriate agencies to address issues and program activities related to improving coordinated school health programs; and strengthen the capacity of post-secondary institutions and youth-serving agencies to prevent foodborne illness through coordinated school food safety programs.

2. CDC Activities

a. Provide and periodically update information related to the purposes or activities of this program announcement.

b. Coordinate with national, state, and local education, health and social service agencies as well as other relevant organizations in planning and conducting national strategies designed to prevent foodborne illness through coordinated school food safety programs.

c. Provide programmatic consultation and guidance related to program planning, implementation, and

evaluation; assessment of program objectives; and dissemination of successful strategies, experiences, and evaluation reports.

d. Plan meetings of national, state, and local education agencies and other appropriate agencies to address issues and program activities related to improving coordinated school health programs; and strengthen the capacity of postsecondary institutions and youth-serving agencies to prevent foodborne illness through coordinated school food safety programs.

e. Assist in the evaluation of program activities.

E. Application Content

Use the information in the Purpose, 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 the criteria as you construct your program plan. The narrative should be no more than twenty (20) double-spaced pages, printed on one side, with one inch margins, and unredacted font.

1. Background (No More Than 4 Pages)

a. Describe your organization's current structure (mission, goals and its primary constituency). Describe how that structure can support school-based food safety programs that are part of a coordinated school health program, including the potential role of your organization's primary constituency in a school food safety initiative. Identify current gaps in the existing structure and implementation of school-based food safety programs and discuss how your constituency can enhance the state and local education agencies' ability to deliver an optimal food safety program.

b. Describe your organization's constituency experience in assisting the state education, state health and state agriculture departments' current school food safety program. Include in your description constituency experience assisting these agencies' use of existing protocols, training, and educational materials available from the USDA and FDA related to food safety and foodborne illness outbreaks. Describe barriers within state and local education agencies to effectively reporting foodborne illnesses and outbreaks and indicate how your organization and constituency can build that capacity.

c. Describe your organization's experience in developing and implementing policy related to food safety programs and reporting school-based foodborne outbreaks. Discuss potential limitations to existing policies

and describe, if any, the need for new policies that address school food safety and the prevention of foodborne illness.

d. Describe your organization's experience in developing and implementing model policy, curricula, training programs, surveillance activities, and evaluation protocols. Describe your organization's experience providing technical assistance and training.

2. Operational Plan (No More Than 8 Pages)

a. Provide short-term (1-year) and long-term (3-year) objectives for the proposed project that build the capacity of coordinated school food safety programs nationwide. The objectives must be specific, time-phased, measurable, and realistic. The proposed objectives should compliment ongoing activities related to "From Farm to Table: A National Food Safety Initiative" (see the U.S. government food safety information gateway website <http://www.foodsafety.gov> for more information on activities related to the National Food Safety Initiative).

b. Submit a plan that proposes first year activities to build the capacity of your organization and others to implement a model food safety program designed to prevent foodborne illness in schools. Include a time-line for the completion of each component or major activity that describes who will do what by when. Examples of acceptable activities can include, but are not limited to the Recipient Activities Described in Section D Program Requirements.

3. Administration and Management (No More Than 2 Pages)

a. Describe how the proposed professional staff will contribute to the overall school food safety program. Describe how the current or proposed placement of each staff will assure that program implementation among state education, health, and agriculture agencies, their affiliates, and partners is coordinated with your organization's constituents.

b. Demonstrate that existing or proposed professional staff have or will have the necessary background and qualifications for the proposed responsibilities. Indicate how your organization can ensure that for each professional working on the project, their position description requires the appropriate level of education and experience related to the level of responsibility and expected duties. A curriculum vitae (no more than two pages for each professional staff) should be included in an appendix to the

application for existing staff who are assigned to this project.

c. In an appendix to the application, provide an organizational chart that identifies lines of communication, accountability, reporting, authority, and describes management and control systems within your organization.

4. Collaboration (No More Than 2 Pages)

a. Describe the organization's current collaboration with states' health, education, and agricultural departments. Describe your organization's collaboration with other federal agencies, national non-profit organizations, foundations, community-based groups, and others who have an interest in or whose mission includes food safety programs, whether their efforts are school-based or not. Discuss how your collaborative relationship can strengthen this project. Indicate who you propose to collaborate with to implement the proposed Operational Plan. Include letters of participation and support documenting these anticipated collaborations. In particular, describe how the proposed activities compliment or build on existing food safety programs.

b. Describe collaborative activities or anticipated relationships with other national organizations who support school-based health education programs. Include letters of participation and support documenting these anticipated collaborations. In particular, describe how your organization can compliment the activities of existing national organizations and how their expertise can support this proposed project.

5. Evaluation Plan (No More Than 2 Pages)

Describe plans to evaluate progress in meeting objectives and conducting activities during the budget period. Specify what data will be obtained and present a plan that includes how the data will be obtained, disseminated, and used to improve the program. Indicate in the plan who will do what and when.

6. Budget and Justification (No More Than 2 Pages)

Provide a detailed budget and line-item justification for all operating expenses that are consistent with proposed objectives and planned activities. The budget should include funds for travel to two CDC meetings during the budget year.

F. Submission and Deadline

Application Content

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit. Submit the application kit on or before August 1, 2000, to the Grants Management Specialist (GMS) identified in the "Where to Obtain Additional Information" section of this announcement.

Deadline: Applications will 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. (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 are not 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 considered, and will be returned to the applicant.

G. Evaluation Criteria

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

1. Background and Need (30 Points)

a. (10 points) The extent to which the applicant describes the current organizational structure, how that structure can support school-based food safety programs, and identifies current gaps in the existing structure of state agencies that decreases the states' ability to deliver an optimal food safety program.

b. (10 points) The extent to which the applicant discusses barriers within states to using existing resources that contribute to the prevention of foodborne illnesses, describes experience in assisting state education, state health and state agriculture departments' current school food safety programs and describes experience assisting state agencies' use of existing protocols, training, and educational materials.

c. (5 points) The extent to which the applicant describes experience in developing policy related to food safety programs and reporting school-based foodborne outbreaks, discusses gaps in the existing policy at the state level and discusses a proposal for new policy.

d. (5 points) The extent to which the applicant describes experience in developing and implementing model

policy, curricula, training programs, surveillance activities, and evaluation protocol and describes your organization's experience providing technical assistance and training.

2. Operational Plan (30 Points)

a. (15 Points) The extent to which the applicant provides short-term (1-year) and long-term (3-year) objectives for the proposed project that build the capacity of coordinated school food safety programs nationwide. The objectives must be specific, time-phased, measurable, and realistic. The proposed objectives should compliment ongoing activities related to "From Farm to Table: A National Food Safety Initiative" (see the U.S. government food safety information gateway website, <http://www.foodsafety.gov>, for more information on activities related to the National Food Safety Initiative).

b. (15 points) The extent to which the applicant submits a plan that builds the capacity of its constituents and others to assist state and local education agencies in establishing a model school food safety program designed to prevent foodborne illness and includes a timeline for the completion of each component or major activity that describes who will do what by when. The extent to which the proposed activities are comparable to the identified Recipient Activities Described in Section D Program Requirements.

3. Administration and Management (15 Points)

a. (5 points) The extent to which the applicant provides job descriptions for existing and proposed professional positions and describes how the proposed professional staff will contribute to the overall school food safety program. To the extent to which the applicant describes how the current or proposed placement of each staff will assure that program implementation among state education, health, and agriculture agencies, their affiliates, and partners is coordinated with the organization's constituents.

b. (5 points) The extent to which the applicant demonstrates that existing or proposed staff have or will have the necessary background and qualifications for the proposed responsibilities and indicates how the organization can ensure that for each professional working on the project, their position description requires the appropriate level of education and experience related to the level of responsibility and expected duties. The extent to which the applicant provides a curriculum

vitae for existing staff who are assigned to this project.

c. (5 points) The extent to which the applicant provides an organizational chart that identifies lines of communication, accountability, reporting, authority, and describes management and control systems within the organization and discusses how the proposed placement of the project in the organization will increase its likelihood of success.

4. Collaboration (20 Points)

a. (15 points) The extent to which the applicant describes current collaboration with states' health, education, and agricultural departments, the organization's collaboration with other federal agencies, national non-profit organizations, foundations, community-based groups, and others who have an interest in or whose mission includes food safety programs, and discusses how the current collaborative relationships can compliment the proposed project. The extent to which the applicant indicates proposed collaborative relationships that will support the proposed operational plan and includes letters of participation and support documenting these anticipated collaborations especially with proposed activities.

b. (5 points) The extent to which the applicant describes collaborative activities or anticipated relationships with other national organizations who support school-based health education programs, and includes letters of participation and support documenting these anticipated collaborations. The extent to which the applicant describes how the organization can compliment the activities of existing organizations and how their expertise can support this proposed project.

5. Evaluation Plan (5 Points)

The extent to which the applicant describes their plan to evaluate progress in meeting objectives and conducting activities during the budget period including their ability to describe: (1) What data will be obtained; (2) how the data will be obtained; (3) how evaluation information will be disseminated; (4) how the evaluation data will be used to improve the program; and (5) who will implement the evaluation plan and when.

6. Budget and Justification (Not Scored)

The extent to which the budget is reasonable and consistent with the purposes and activities of the program.

H. Other Requirements

Technical Reporting Requirements

1. Provide CDC with original plus two copies of the progress report, submitted on an annual basis and due 90 days after the end of the budget period. The progress reports must include the following for each program, function, or activity involved:

- A comparison of actual accomplishments to the objectives established for the period;
- Documentation on why established objectives were not met; and
- A summary of the project's annual progress in achieving performance measures, which will be developed and established in collaboration with CDC during the first budget period.

2. Provide CDC with original plus two copies of the financial status report, no more than 90 days after the end of the budget period.

3. Final financial and progress reports, no more than 90 days after the end of the project period, should be sent to the business management contact listed in Section J, "Where to Obtain Additional Information."

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-8 Public Health System Reporting Requirement
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-20 Conference Support

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 311(b) and (c), and 317 (k)(2) [42 U.S.C. 241(a), 243(b) and (c), and 247b(K)(2)] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.938.

J. Where To Obtain Additional Information

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Jesse Robertson, Grants Management Specialist, Grants Management PA00109, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd, M/S E18, Atlanta,

Georgia 30341-4146, telephone (770) 488-2747, jtr4@cdc.gov.

This and other CDC announcements can be found on the CDC Homepage Internet address: <http://www.cdc.gov> Also, CDC Guidelines to Promote Healthy Eating: <http://www.cdc.gov/nccdphp/dash/nutguide.htm> and CDC Guidelines to Promote Physical Activity: <http://www.cdc.gov/nccdphp/dash/physact.htm>

For program technical assistance, contact: Pete Hunt, Chief, School Program Section, Program Development and Services Branch, Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, Announcement 00109, Centers for Disease Control and Prevention, 4770 Buford Highway, NE MS K31, Atlanta, GA 30341, telephone: 770-488-3253, pch0@cdc.gov.

Dated: June 13, 2000.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1311]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Medical Devices—Foreign Letters of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on collection of information requirements for reporting requirements for firms that intend to export certain unapproved medical devices.

DATES: Submit written comments on the collection of information by August 21, 2000.

ADDRESSES: Submit written comments on the collection of information to the