

By the Federal Maritime Commission.
Joseph C. Polking,
 Secretary.
 [FR Doc. 95-12669 Filed 5-23-95; 8:45 am]
 BILLING CODE 6730-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 537]

State Grants To Support Development and Evaluation of Nutrition Intervention Programs

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for grants to support the development and evaluation of State and community nutrition intervention programs.

This announcement addresses two distinct components:

I. "Nutrition Intervention Assistance" for supporting the implementation of nutrition interventions.

II. "5 A Day Evaluation" for supporting the evaluation of 5 A Day for Better Health nutrition intervention programs.

Applicants may apply for either the Nutrition Intervention Assistance component or the 5 A Day Evaluation component or both components.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related specifically to the priority area of Nutrition and, generally, to several other priority areas of health promotion and preventive services—including Physical Activity and Fitness, Heart Disease, Cancer, and Diabetes. (For ordering a copy of "Healthy People 2000," see the Section, "Where to Obtain Additional Information.")

Authority

This program is authorized under section 317(k)(2) (42 U.S.C. 247b (k)(2)) of the Public Health Service Act, as amended.

Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994,

prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

A. Nutrition Intervention Assistance

Assistance will be provided only to the health departments of States or their bona fide agents. This includes American Samoa, the Commonwealth of Puerto Rico, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments. Excluded are the States, territories and American Indian tribes of: Alaska, Alabama, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Hawaii, Iowa, Kansas, Massachusetts, Maine, Montana, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New York, North Dakota, Ohio, Rhode Island, Tennessee, Texas, Utah, Vermont, West Virginia, Washington, Bristol Bay Area Health Corporation, Poarch Band of Creek Indians, Mississippi Band of Choctaw Indians, Miccosukee Corporation, and the Virgin Islands, which were funded for nutrition intervention activities under Program Announcement 494, entitled State Grants to Support Development and Evaluation of Nutrition Intervention Programs.

B. 5 A Day Evaluation

Assistance will be provided only to the health departments of States or their bona fide agents. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

Eligibility for this component is restricted to States who have established, clearly defined, evaluable, long range 5 A Day for Better Health projects in a specific community channel.

Eligible applicants for nutrition intervention program grants have been restricted to official health departments of States or their bona fide agents or instrumentalities because:

1. The methodology to conduct this program has been structured to support the national goals and objectives of "Healthy People 2000." In many instances, State health departments have already embraced or established

their own goals and objectives which match or are synonymous with those outlined in "Healthy People 2000."

2. The conduct of Statewide health promotion, health education, and risk reduction programs directed towards reducing the prevalence of behavioral risks in the population lies solely with State Health Departments.

3. Program evaluation is expected to be useful to State Health Departments in program and intervention development. Because comparable methods are used from State to State and from year to year, States can compare data and intervention methods with other States and monitor the effects of interventions over time.

Availability of Funds

Approximately \$740,000 is available in FY 1995 to fund approximately 22 awards. Awards may be made for the Nutrition Intervention Assistance, or 5 A Day Evaluation or both.

A. Nutrition Intervention Assistance

Approximately \$450,000 is available to fund approximately 18 awards. It is expected that the average award will be \$25,000 ranging from \$18,000 to \$32,000. States are encouraged to use these funds to expand the community involvement toward the goals of this program.

B. 5 A Day Evaluation

Approximately \$290,000 is available to fund approximately 4 awards. It is expected that the average award will be \$75,000 ranging from \$60,000 to \$90,000. Awards will be considered only for applicants who have an established, clearly defined, and evaluable long range 5 A Day for Better Health project in a specific community channel (e.g., supermarkets, schools, churches, food assistance programs, worksites, health clinics, media, etc.).

It is expected that the awards will begin on or about September 28, 1995, and will be made for a 12-month budget period within a project period of one year. Funding estimates may vary and are subject to change.

Awards under this announcement will not be sufficient to fully support an applicant's proposed activities, but are meant to be used in conjunction with other resources—whether direct funding or in-kind contributions—that the applicant may have available.

Purpose

The awards will support State efforts to develop and evaluate nutrition intervention programs. Emphasis will be placed on supporting activities of partnerships to carry out interventions

and/or evaluations designed to increase the consumption of fruits and vegetables, to decrease fat intake, and/or to increase physical activity while improving diet.

Program Requirements

A. Nutrition Intervention Assistance

Promote programmatic activities to achieve Healthy People 2000 dietary objectives that relate to increased consumption of fruits and vegetables, reduced intake of fat, and/or improving diet while increasing physical activity. Applicants should propose specific and discrete activities, but applicants are given latitude in deciding which specific activities to propose. Activities proposed by applicants might include but are not limited to the following:

1. Assist a Statewide or community-wide coalition to implement a 5 A Day for Better Health project by using effective public and private partnerships.
2. Implement an intervention to promote physical activity and improved diet among a defined low-income population.

3. Evaluate a health communication campaign. (Such campaigns could be broad-based, could target specific populations, or could support specific programs, such as Project LEAN or 5 A Day for Better Health.)

4. Integrate a nutrition education component into an existing State chronic disease program (e.g., diabetes, cancer, and heart disease prevention programs) or into appropriate services of a managed care provider.

B. 5 A Day Evaluation

An evaluation of a 5 A Day intervention in a specific community channel. Applicants should propose a plan for an evaluation of a clearly defined, long range effort in a specific community channel.

Evaluation Criteria

Applications for the Nutrition Intervention Assistance and the 5 A Day Evaluation components will be allocated 100 points each and will be reviewed and evaluated according to the following criteria:

A. Nutrition Intervention Assistance

1. Background

The degree to which the applicant succinctly describes the problems to be addressed and current activities for resolving them. (10 points)

2. Objectives

The degree to which objectives are realistic, time-phased, measurable, and specific. (20 points)

3. Program Plan

The adequacy of the applicant's plan to carry out the proposed activities and accomplish the stated objectives. (40 points)

4. Program Integration

The adequacy of the applicant's commitment to provide sufficient staff and resources necessary to achieve the program objectives. (20 points)

5. Evaluation

The extent to which the applicant presents a reasonable plan to measure progress in meeting objectives and evaluate performance. (10 points)

6. Budget

The extent to which the applicant provides a detailed budget and line item justification that is consistent with the stated objectives, program purpose, and planned activities of the project. (not weighted)

B. 5 A Day Evaluation

1. Background

The degree to which the applicant clearly describes a long range, clearly defined, evaluable 5 A Day for Better Health project, including a description of the intervention method and channel. (25 points)

2. Program Plan

The adequacy of the applicant's plan to carry out the evaluation, including the specific objectives and measures in the evaluation. (45 points)

3. Capacity

The capabilities of the personnel (including consultants where appropriate) to carry out the evaluation. (30 points)

4. Budget

The extent to which the applicant provides a detailed budget and line item justification that is consistent with the evaluation plan. (not weighted)

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is

advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Clara M. Jenkins, Grants Management Officer, 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, no later than 60 days after the application deadline date. The Program Announcement Number and Program Title should be referenced on the document. CDC does not guarantee to "accommodate or explain" State process recommendations it receives after the date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to Clara M. Jenkins, Grants Management Officer, 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. This should be done no later than 60 days after the application date. The granting agency does not guarantee to "accommodate or explain" for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.283.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (OMB Number 0937-0189) must be submitted to Clara M. Jenkins, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers For Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E-13, Atlanta, GA 30305, on or before June 30, 1995.

1. 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 objective 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 accepted as proof of timely mailing.)

2. Late Applications: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Albertha Carey, 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, Mail Stop E-13, Atlanta, GA 30305, telephone (404) 842-6508.

Programmatic technical assistance may be obtained from Judy Pruden, M.Ed., R.D., Division of Nutrition, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mail Stop K-26, Atlanta, GA, 30341-3724, telephone (404) 488-4260.

Please refer to Announcement Number 537 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report; Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report; Stock No. 017-001-00473-1) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: May 15, 1995.

Joseph R. Carter

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC)

[FR Doc. 95-12762 Filed 5-23-95; 8:45 am]

BILLING CODE 4163-18-P

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Oncologic Drugs Advisory Committee

Date, time, and place. June 8 and 9, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, June 8, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open committee discussion, June 9, 1995, 8 a.m. to 11:30 a.m.; closed committee deliberations, 11:30 a.m. to 4 p.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make

formal presentations should notify the contact person before June 5, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On June 8, 1995, the committee will discuss: (1) New drug application (NDA) 50-704, Daunoxome® Injection (liposomal daunorubicin, Vestar, Inc.) "as the primary therapy for the palliative management of advanced, HIV-associated Kaposi's Sarcoma," and (2) NDA 20-449, Taxotere® (docetaxel, Rhone-Poulenc Rorer), for treatment of "patients with locally advanced or metastatic breast carcinoma in whom previous therapy has failed; prior therapy should have included an anthracycline unless clinically contraindicated." On June 9, 1995, the committee will discuss NDA 20-221, Ethyol (amifostine injection, U.S. Bioscience, Inc.) "as a cytoprotective agent against the cumulative renal toxicities associated with cisplatin and the cumulative hematologic toxicity associated with cyclophosphamide and cisplatin in patients with advanced solid tumors of non-germ cell origin."

Closed committee deliberations. On June 9, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to investigational new drugs (IND's) and pending NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. June 12, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 and reference the FDA panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 12 m.; closed committee deliberations, 12 m. to 1:30 p.m.; open public hearing, 1:30 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 5 p.m.; Paula J. Wilkerson,