

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention**

[Program Announcement 98079]

State Grants to Support the Evaluation of 5 A Day Nutrition Programs**Introduction**

The Centers for Disease Control and Prevention (CDC), in partnership with the National Cancer Institute (NCI), announces the availability of fiscal year (FY) 1998 funds for grants to support the evaluation of State and community 5 A Day nutrition intervention programs. This announcement addresses one required component, which is the "5 A Day Evaluation" for supporting the evaluation of 5 A Day for Better Health nutrition intervention programs. CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related specifically to the priority area of Nutrition. (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

CDC encourages all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products, and Pub. L. 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

Eligible applicants are the official public health agencies 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, that have established, clearly-defined, measurable, long-range 5 A Day for Better Health projects in a specific community channel.

Availability of Funds

Approximately \$450,000 is available in FY 1998 to fund approximately 6 awards. It is expected that the average award will be \$75,000 ranging from \$55,000 to \$90,000 for a 5 A Day for Better Health project in a specific community channel, preferably focusing on interventions in minority-based population subgroups (i.e. American Indian, Asian, Pacific Islander, African American, Hispanic, elderly, low socioeconomic status, or the very young). It is expected that the awards will begin on or about September 30, 1998, 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.

Restrictions On Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. section 1352 (which has been in effect since December 23, 1989), recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grants cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby. In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Pub. L. 105-78) states in Section 503(a) and (b) no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relations, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislative body itself. No part of any appropriation contained in this Act shall be used to

pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

The Surgeon General's Report on Nutrition and Health in 1988 noted that two-thirds of all deaths are due to diseases associated with diet. The report also says that the three most important personal habits that influence health are smoking, alcohol consumption, and diet. For the two out of three adults who do not drink alcohol excessively or smoke, the single most important personal choice influencing long-term health is what they eat. Improving dietary intake and physical activity levels of minority populations (American Indian, Asian, Pacific Islander, African American, Hispanic, elderly, low socioeconomic status, or the very young) could substantially extend productive lives and reduce the human and financial costs of chronic disease, disability, and premature death within population subgroups that suffer a disproportionate cancer burden.

Using effective nutrition education strategies to reach under served minority populations in order to initiate successful behavior change are critical since healthy eating practices are more likely to be obtained with well-developed, culturally-sensitive, linguistically appropriate intervention methods that are effective in reaching the targeted audience and assist in transforming the local environment. Modifications in the environment help promote, support, and institutionalize healthy eating practices, and as this transformation occurs in various channels, community norms will be transformed also. Culturally sensitive and linguistically appropriate interventions combined with environmental support can promote lifelong healthy eating practices. The Healthy People 2000 national objectives include an objective intended to reduce the current high burden of chronic disease and premature death: increase fruit and vegetable intake (from 2.5 to 5 servings per day). To date, progress is slow achieving this objective through culturally specific, linguistically appropriate interventions and environmental community approaches, especially among minorities and economically disadvantaged Americans who are at increased risk for many chronic diseases. The 5 A Day for Better Health Program is a nationwide effort, lead by the National Cancer Institute (NCI), to achieve the Healthy People

2000 objective for five or more servings per day of fruits and vegetables. The CDC is collaborating with NCI to support the activities of State health departments in the implementation and evaluation of the State 5 A Day activities.

Purpose

These awards will support State efforts to evaluate 5 A Day nutrition intervention programs. Emphasis will be placed on:

(1) Evaluation of a community intervention's impact on knowledge, attitude, awareness and behavioral change in minority-based population groups (such as elderly, young children or low-income groups, and ethnic groups such as, but not exclusive to, American Indians, Asians, Pacific Islanders, African Americans or Hispanics) which have low fruit and vegetable intakes or have a disproportionately greater risk for cancer;

(2) Testing the effects of culturally sensitive and linguistically appropriate strategies within a community intervention designed to increase the consumption of fruits and vegetables in minority population subgroups and promote other related lifestyle behaviors which are recognized covariates that influence fruit and vegetable consumption; or

(3) Evaluation of communication channels (radio, tv, print media) which target the specific minority population subgroups identified as part of 5 A Day-based community intervention campaigns.

Program Requirements

Applicants should propose an evaluation plan for a clearly defined, established, long-range effort in one or more specific community channels in accordance with the following definitions:

A. Clearly Defined

Intervention objectives are clearly stated; activities necessary to accomplish objectives are described, to include who is responsible for each activity and when they will be accomplished; and work is done within a specific channel with a defined targeted audience.

B. Established

The applicant is licensed with NCI and has developed an ongoing 5 A Day Program. Evaluating pretested or piloted interventions is desirable.

C. Evaluation Plan

Clear, measurable evaluation objectives and expected outcomes are defined with appropriate statistical power. Use of current theoretical frameworks to guide the evaluation study is desirable. A combination of process and impact objectives is also desirable, with outcome objectives where feasible. In designing the study, consideration should be given to the number of individuals or groups needed to detect realistic changes in post-intervention outcome measures when compared with pre-intervention measures. Sample sizes should give adequate power (80 percent) to detect these changes. If the appropriate design expertise does not exist within the State health department, inclusion of an organization with the necessary design expertise on the project team, such as a university affiliate, is recommended.

D. Long Range

The program is not just a single activity at one point in time, but a sustained effort involving appropriate behavior change strategies. Programs including environmental approaches, such as administrative changes, are encouraged.

Technical Reporting Requirements

An original and two copies of a final progress report and financial status report are required no later than 90 days after the end of the budget/project period. Final financial and performance reports are required no later than 90 days after the end of the budget/project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

The progress reports must include the following for each program, function, or activity involved: (1) A comparison of the actual accomplishments to the goals established for the period; (2) the reasons for slippage if established goals were not met; and (3) other pertinent information including, when appropriate, analysis and explanation of unexpectedly high costs for performance.

Application Content

Applications must be developed in accordance with Form PHS-5161-1 (Revised May 1996, OMB Number 0937-0189), information contained in this program announcement, and instructions provided in this section.

A 10-page narrative, excluding the budget and attachments, is required and must contain the following information:

A. Background

Provide a brief but clear description of a current long-range project in one or more specific community channels including project goals and objectives, target group, methodology of intervention, and length of time of the current project.

B. Program Plan

Provide a realistic, time phased, and specific work plan including evaluation goals, objectives, methods, and outcomes to be achieved during the 12-month period; and a clear plan to evaluate the current long-range effort in a particular channel or channels and assess the impact of those activities with measures of process and outcomes related to the targeted audience. Examples of potential evaluation projects might include but are not limited to the following:

a. Evaluation of the process and impact of instituting a community neighborhood 5 A Day project targeting for example minority, elderly, youth, or low-income groups and its effect on perceived barriers, attitudes, beliefs, dietary behaviors and fruit and vegetable consumption.

b. Evaluation of innovative measurement techniques appropriate for targeted minority audiences and their perceptions/response to the current 5 A Day Program recommendations of 5 to 9 servings of fruits and vegetables daily.

c. Evaluate the impact of a 5 A Day media and/or education campaign on knowledge, attitudes, and behaviors of targeted minority community members, with a focus on issues of awareness translating to action/behavioral stages of change and changes in fruit and vegetable consumption. (e.g. food assistance program like Women Infant Children (WIC) or other community-based program combined with a media intervention).

d. Evaluate an intervention that promotes healthy dietary choices (5 A Day) and physical activity in a defined community setting with a focus on the effect of affiliated environmental change(s) on behavior.

C. Capacity

Document the expertise of the evaluation team by including the curriculum vitae (limited to 1 page attachment per person) for key members of the team. If sufficient evaluation expertise is not available in the State health department, States are strongly encouraged to work with an academic institution in the design, data collection, and analysis activities for this evaluation. For interventions involving

administrative changes, describe the infrastructure that is or will be in place to support the administrative change once made in the defined setting.

D. Human Subjects

Documentation that human subject assurances are met, either through copies of approved protocols or notation of the institutional review committee that will review the project, particularly if the intervention targets children or pregnant women. Should human subjects review be required, the proposed work plan should incorporate time lines for such development and review activities.

E. Budget

Provide a detailed budget and line-item justification that is consistent with the stated objectives, purpose, and planned activities of the project. (Not to be counted as part of the 10 page narrative.)

An original and two copies of the application are required. Pages should be numbered, and an index to the application and appendix must be included. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, single-spaced, with unreduced type on 8½" by 11" paper, with at least 1" margins, headers and footers, and printed on one side only. Materials that should be part of the basic plan will not be accepted if placed in the appendix. Appendix material should not exceed 25 pages. Please do not include reports (or portions thereof), journal articles, mass media articles, or presentations of national statistical data.

Evaluation Criteria (100 Points)

Applications will be reviewed and evaluated according to the following criteria:

A. Background: (25 Points)

The degree to which the applicant clearly describes a long-range, clearly defined, measurable project, including a description of the intervention targeted population, method, and community channel(s).

B. Program Plan: (45 Points)

The adequacy of the applicant's plan to carry out the evaluation within the 12-month time period, including the specific objectives, methods, and measures to be used in the evaluation.

C. Capacity: (30 Points)

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

D. Human Subjects: (Not Weighted)

Whether or not exempt from the Department of Health and Human Services (HHS) regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and there are concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

E. Budget: (Not Weighted)

The extent to which the applicant provides a detailed budget and line-item justification that is consistent with the evaluation plan.

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 of 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 Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E-18, Atlanta, Georgia 30305, no later than 30 days after the application deadline. The Program Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to "accommodate or explain" State process recommendations it receives after that 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 Sharron P. Orum, Grants Management Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E-18, Atlanta, Georgia 30305. This should be done no later than 30 days after the application deadline. 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.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit. Should human subjects review be required, the proposed work plan should incorporate time lines for such development and review activities.

Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC-supported research projects involving

human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino. Applicants shall ensure that women and racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947-47951.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (Revised 5/96, OMB Number 0937-0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers For Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E-18, Atlanta, GA 30305, on or before July 1, 1998.

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 and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information, call (888) 472-6874. You will be asked to leave your name, address, and telephone number. Please refer to Announcement 98079. You will

receive a complete program description, information on application procedures, and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Sheryl L. Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E-18, Atlanta, GA 30305, telephone (404) 842-6802; electronic mail at slh3@cdc.gov.

Programmatic technical assistance may be obtained from Sarah Kuester, MS, RD, Division of Nutrition and Physical Activity, 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 (770) 488-6019, fax (770) 488-6000, or Internet or CDC WONDER electronic mail at sak2@cdc.gov.

You may obtain this announcement from CDC's homepage at <http://www.cdc.gov>.

Please refer to Program Announcement 98079 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: June 1, 1998.

John L. Williams,

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

[FR Doc. 98-15122 Filed 6-5-98; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0362]

Draft Guidance for Industry on Stability Testing of Drug Substances and Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a draft guidance for industry entitled "Stability Testing of Drug Substances and Drug Products." The draft guidance provides recommendations regarding the stability studies that should be performed to support new drug applications, abbreviated new drug applications, investigational new drug applications, biologics license applications, product license applications, and supplements to these applications.

DATES: Written comments on the draft guidance may be submitted by September 9, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>. Submit written requests for single copies of the draft guidance entitled "Stability Testing of Drug Substances and Drug Products" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Kenneth J. Furnkranz, Center for Drug Evaluation and Research (HFD-625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855-2737, 301-827-5848, or
Rebecca A. Devine, Center for Biologics Evaluation and Research (HFM-10), 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Stability Testing of Drug Substances and Drug Products." The draft guidance provides recommendations regarding the stability studies that should be performed by pharmaceutical applicants to support applications submitted to the Center for