B. Applications

Applicants should use Form PHS–398 (OMB Number 0925–0001) and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and five copies on or before April 16, 1998 to: Ron Van Duyne, Grants Management Officer, ATTN: Joanne Wojcik, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, MS E–13, Atlanta, GA 30305.

C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

a. Received at the above address on or before the deadline date, or

b. Sent on or before the deadline date to the above address, and received in time for the review process.

Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailings.

2. Applications which do not meet the criteria above are considered late applications and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call 1–888–GRANTS4. You will be asked your name, address, and telephone number and will need to refer to Announcement 817. You will receive a complete program description, information on application procedures, and application forms. In addition, this announcement is also available through the CDC Home Page on the Internet. The address for the CDC Home Page is (http://www.cdc.gov).

If you have questions after reviewing the contents of all the documents, business management information may be obtained from 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., MS E–13, Atlanta, GA 30305, telephone (404) 842–6535; fax: (404) 842–6513; Internet: jcw6@cdc.gov.

Programmatic technical assistance may be obtained from Roy M. Fleming, Sc.D., Director Research Grants Program, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Building 1, Room 3053, MS–D30, Atlanta, GA 30333, telephone 404–639–3343; fax 404–639–4616; internet: rmf2@cdc.gov.

Please refer to announcement number 817 when requesting information and submitting an application.

This and other CDC Announcements can be found on the CDC homepage (http://www.cdc.gov) under the ''Funding'' section, as well as on the NIOSH homepage (http://www.cdc.gov/niosh/homepage.html) under ''Funding Opportunities/Extramural Programs.'' For your convenience, you may be able to retrieve a copy of the PHS Form 398 from (http://www.nih.gov/grants/funding/phs398/phs398.html). CDC will not send application kits by facsimile or express mail.

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) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Useful References

The following documents may also provide useful information: National Committee for Childhood Agricultural Injury Prevention. Children and Agriculture: Opportunities for Safety and Health. Marshfield, WI: Marshfield Clinic, 1996.

National Institute for Occupational Safety and Health. National Occupational Research Agenda. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 96–115 (http://www.cdc.gov/niosh/nora.html).

Dated: January 14, 1998.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–1331 Filed 1–20–98; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 98019]

Fiscal Year 1998 Pfiesteria-Related Illness Surveillance and Prevention

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for cooperative agreements for Pfiesteria-Related Illness Surveillance and Prevention. These cooperative agreements are intended to strengthen and provide interstate uniformity for surveillance programs, epidemiologic and laboratory investigations, prevention and control activities, and identification of exposed cohorts at the State and local levels.

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 to the priority area of Environmental Health. (For ordering a copy of Healthy People 2000, see the section **Where to Obtain Additional Information**.)

Authority

This program is authorized under section 301(a) and 317 of the Public Health Service Act, (42 U.S.C. 241(a) and 247b), as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds and in which education, library, day care, health care, and early childhood development services are provided to children.

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of 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 subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, 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 current HHS Appropriations Act expressly prohibits the use of appropriated funds for indirect or grass roots lobbying efforts that are designed to support or defeat legislation pending before State legislatures.

Section 503 of the law provides as follows:

(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, 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 legislature itself.

(b) 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.

Eligible Applicant

Applicants will be limited to the official State public health departments of States having confirmed (i.e., cases meeting the CDC set of exposure criteria and clinical signs and symptoms for Pfiesteria) or suspected cases of Pfiesteria-related illness that are being investigated by State health departments, or those States with coastal waters that have been infected by Pfiesteria or Pfiesteria-like organisms.

The CDC set of exposure criteria and clinical signs and symptoms for Pfiesteria are defined as: Exposure to estuarine water characterized by one of the following: (1) Fish with lesions consistent with *Pfiesteria piscicida* or morphologically related organisms (MRO) toxicity (20 percent of at least 50 fish of one species having lesions); (2) a fish kill with fish having lesions consistent with Pfiesteria or MRO toxicity; or (3) a fish kill involving fish without lesions, in the presence of Pfiesteria or MRO, without an alternative reason for the fish kill. The clinical features include the following signs and symptoms: (1) Memory loss, (2) confusion, (3) acute skin burning (upon direct contact with water), or (4) three or more of the following: a. headaches; b. skin rash; c. eye irritation; d. upper respiratory irritation; e. muscle cramps; f. nausea/vomiting/diarrhea/abdominal cramps.

Availability of Funds

Up to $3.5 million will be available in FY 1998 to fund up to 8 awards. Awards for the initial budget period will be based upon the extent of the problem and are expected to range from approximately $150,000 to $450,000. The awards will be made on or about March 15, 1998, for a 12-month budget period and a project period of up to 5 years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The purpose of the Pfiesteria-related Surveillance and Prevention Program is to assist State/local public health departments with: (1) Surveillance activities for adverse human health outcomes and exposure to infected waters; (2) epidemiologic studies including objective review of human health outcomes; (3) laboratory investigations; and (4) prevention and control activities.

Program Requirements

Cooperative Activities

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under A. (Recipient Activities), and CDC will be responsible for conducting activities under B. (CDC Activities).

A. Recipient Activities

The following activities should be planned and conducted in collaboration and coordination with CDC by State/local health departments, and, where appropriate, in consultation with:

—Appropriate State and local professional associations;
—Health care providers and institutions serving, diagnosing, or providing treatment and care for persons having Pfiesteria-related symptoms, including laboratories conducting testing;
—Community groups and organizations.
—Universities and health research agencies.

Specific surveillance and prevention activities should:

1. Identify individuals with high risk of exposure to Pfiesteria-infected waters.

2. Conduct investigation of all cases of Pfiesteria-related illnesses meeting the CDC set of exposure conditions and clinical signs and symptoms to determine risk factors for illness and to provide clinical materials for laboratory confirmation.

3. Develop and conduct surveillance activities to identify potential sources of exposure to Pfiesteria or Pfiesteria-like organisms, and provide samples to CDC for additional laboratory analysis.

4. Assess clinical data on persons with Pfiesteria-related illnesses to assist in guiding the development of treatment strategies.

5. Develop and implement appropriate prevention strategies and develop information materials for use by health professionals and the public to aid in prevention and control of Pfiesteria-related illness.

B. CDC Activities

1. Provide consultation and scientific and technical assistance and training, in planning, implementing, and evaluating Pfiesteria exposure cohort studies, surveillance, epidemiologic research, laboratory and prevention activities.

2. Assist in developing a format for reporting surveillance data including case report forms, database, and assistance in establishing and maintaining the reporting system.

3. Bank and conduct laboratory analysis of biological specimens.

4. Participate with States to finalize mutually agreed upon standardized study protocols and, where appropriate, data collection instruments for the projects/studies.

5. Coordinate clinical evaluations and studies to assure comparability of data and therapeutic protocols.

6. Provide or assist in preparing standard data collection forms, questionnaires, etc., as needed in surveillance activities and special epidemiologic investigations.

7. Assist in the evaluation of the overall effectiveness of program operations, including the impact of surveillance data on the development of public policy, and on targeting and evaluating prevention activities.

8. Participate in the analysis of information and data gathered from program activities and facilitate the transfer of information and technology among all States and communities.

Technical Reporting Requirements

An original and two copies of a semiannual progress report must be submitted 30 days after the end of each semiannual period. Final financial and performance reports are due no later than 90 days after the end of the project period. All reports will be submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Application Content

Applications must be developed in accordance with PHS Form 5161–1 (OMB Number 0937–0189), information contained in the program announcement and the instructions and format provided below.

1. Abstract

A one-page, single spaced, typed abstract must be submitted with the application. The heading should include the title of the grant program, project title, organization name and address, project director and telephone number. The abstract should briefly summarize the program for which funds are requested, the activities to be undertaken, and the applicants's organization and composition. The abstract should follow application forms and precede the Program Narrative.

2. Program Narrative

The Program Narrative should specifically address all items in the **Program Requirements** section of this announcement. The applicant should provide a description of the planned first year activities, and briefly describe future year objectives and activities. The criteria listed in the **Evaluation Criteria** section will serve as the basis for evaluating the application; therefore, the narrative of the application should address the following.

a. Applicant's understanding of the problem.

b. Applicant's ability to carry out the project.

c. Technical and program personnel capability.

d. Women, Racial and Ethnic Minorities. A description of the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

e. Budget justification.

f. Human Subjects review: The project involves research on human subjects, and therefore, the applicant must describe and demonstrate that the project has been subject to initial review by an appropriate institutional review committee, and that continuing review will occur. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and Human Subjects Assurance form provided in the application kit.

The Program Narrative section should not exceed 40 double-spaced pages excluding attachments (e.g., resumes, appendices, etc.). Do not include a detailed budget or detailed budget justification as part of the Program Narrative.

An original application and two copies should be submitted. The original and each copy of the application must be submitted unstapled and unbound. All material must be typewritten, double-spaced, with un-reduced type on 8½″ by 11″ paper, with at least 1″ margins, headers and footers, and printed on one side only.

All graphics, maps, overlays, etc., should be in black and white and meet the above criteria.

Omissions or incomplete information may affect the rating of the application.

Evaluation Criteria

Each application will be reviewed and evaluated individually according to the following criteria:

A. Understanding of the Problem—25 Points

Extent to which the applicant understands the purpose and requirements of the program. This includes the extent of the applicant's identification and description of the problem, the realistic presentation of objectives to establish effective surveillance system and prevention programs, and evaluation criteria established to assess surveillance, epidemiologic research, and prevention activities.

B. Ability to Carry Out the Project—25 Points

Degree to which the applicant provides evidence of ability to carry out the proposed project and the extent to which the applicant documents demonstrated capability to achieve the objectives of the proposed program. This may include plans, approaches, and methods to be used in conducting and evaluating surveillance, epidemiologic research, and prevention programs, and may include collaborating with universities or other health research agencies.

C. Technical Approach—20 Points

Degree to which proposed objectives are clearly stated, realistic, measurable, time-phased, and related to the stated purpose of this project. Also, the adequacy of the proposed surveillance, epidemiologic research, and prevention plans to achieve the objectives. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. This includes: (a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (b) The proposed justification when representation is limited or absent; (c) A statement as to whether the design of the study is adequate to measure differences when warranted; and (d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits will be documented.

D. Personnel—20 Points

Extent to which professional personnel involved in this project are qualified, including evidence of experience similar to this project.

E. Plans for Administration—10 Points

Adequacy of plans for administering the project.

F. Funding Requirements—(Not Weighted)

Itemized budget for conducting the project, along with justification, is provided and is reasonable.

G. Human Subjects—(Not Weighted)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR part 46) regarding the protection of human subjects.

Executive Order 12372

Applications are subject to the 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 should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the application and receive any necessary instructions on the State process. Since the proposed project will serve 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 the application submitted to CDC, they should forward them to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E–13, Atlanta, Georgia 30305, no later than 60 days after the receipt date of the application.

The granting agency does not guarantee to ''accommodate or explain'' State 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 for this program 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 and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

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. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that individuals of both sexes and the various 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 Alaska Native, Asian, Black or African American, Hispanic or Latino, and Native Hawaiian or other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exists that inclusion is inappropriate or not reasonable, this situation must be explained as part of the application. 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 (a copy is included in the application kit).

Application Submission and Deadline

The original and two copies of the application, PHS Form 5161–1 (OMB Number 0937–0189), must be submitted to Ron Van Duyne, Grants Management Officer, Attention: Patrick A. Smith, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Room 321, Atlanta, Georgia 30305, on or before February 23, 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 should 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 acceptable proof of timely mailing.)

2. *Late Applications:* Applications which do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications shall not be considered in the current competition for funding and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call 1–888–GRANTS4. You will be asked to leave your name, address, and telephone number and will need to refer to NCEH Announcement 98019. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

Please refer to announcement number 98019 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Patrick Smith, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Atlanta, Georgia 30305, telephone (404) 842–6803, Internet: phs3@cdc.gov.

Programmatic technical assistance may be obtained from Lawrence E. Posey, Health Studies Branch, Division of Environmental Health, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop F–46, Atlanta, Georgia 30333, telephone (770) 488–7350, Internet: lep1@cdc.gov.

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** may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Dated: January 14, 1998.

Joseph R. Carter,

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

[FR Doc. 98–1327 Filed 1–20–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0531]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by February 20, 1998.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed