

President's Council on Physical Fitness and Sports, Room 738H Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-5187.

SUPPLEMENTARY INFORMATION: The President's Council on Physical Fitness and Sports (PCPFS) was established in 1956 by President Eisenhower after published reports indicated that American boys and girls were unfit compared to the children of Western Europe.

The Council has undergone two name and changes and several reorganizations before reaching its present status as a program office within the Office of Public Health and Science in the Department of Health and Human Services. It currently operates under directives issued in Executive Order 12345, as amended. PCPFS serves as a catalyst to promote, encourage, and motivate the development of physical fitness and sports participation for all ages. The primary functions of the Council include (1) to advise the President and Secretary concerning progress made in carrying out the provisions of the Executive Order and recommend to the President and Secretary, as necessary, actions to accelerate progress; (2) to advise the Secretary on matters pertaining to the ways and means of enhancing opportunities for participation in physical fitness and sports actions to extend and improve physical activity programs and services; and (3) to advise the Secretary on State, local, and private actions to extend and improve physical activity programs and services.

This meeting of the Council is being held to apprise members of the status of ongoing Council programs and activities, and to make plans for future directions.

Dated: March 30, 1999.

Sandra. P. Perlmutter,
Executive Director, President's Council on Physical Fitness and Sports.

[FR Doc. 99-8513 Filed 4-6-99; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interagency Committee on Smoking and Health: Notice of Recharter

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the charter for the Interagency Committee on Smoking and Health (ICSH) of the

Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period, through March 19, 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Majestic, Deputy Director, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, NE, M/S K-50, Atlanta, Georgia 30341, telephone 770/488-5709.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 30, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-8568 Filed 4-6-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99066]

Primate Model for Studying the Pathogenesis of Measles Infections and for Development of Improved Measles Vaccines; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program to support research into the pathogenesis of measles virus in a primate model. This program addresses the "Healthy People 2000" priority area of Immunization and Infectious Diseases. The goal of this program is to assist researchers in defining the mechanism of immune protection from measles virus and to use this information to develop improved vaccines for worldwide measles control efforts.

Specifically, the purpose of the program is to achieve the following research goals:

1. Use the rhesus macaque as a primate model for measles infections. Studies should attempt to reproduce disease in rhesus that closely resembles

measles in humans. It will be important to develop viral stocks which can reliably produce disease in rhesus by the intranasal route and to describe the pathogenesis of this disease in the animal host.

2. Characterize the immune response to natural measles disease and measles vaccination. Studies should attempt to measure differences between the immune response in animals receiving measles vaccines to those experiencing infection with a virulent strain. Efforts should be aimed at providing a complete description of the humoral, and especially, the cellular immune responses.

3. Development of improved measles vaccines. Research efforts should be directed at developing and testing novel vaccine formulations that could be used to stimulate an immune response in the presence of maternal antibody. Such vaccines would be used to protect newborns from measles infection or disease during their first year of life. Vaccines that could be used to stimulate or boost immunity in immunocompromized individuals should also be considered.

4. Evaluation of immune response to individual measles virus antigens. Research should be designed to measure the immune response generated by experimental measles vaccines and individual measles antigens. Efforts should be made to identify epitopes on measles proteins which are the most effective in inducing humoral and cellular immune responses in an outbred population.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

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 \$300,000 is available in FY 1999 to fund approximately two awards. It is expected that the average award will be \$150,000, ranging from \$100,000 to \$200,000. It is expected that the awards will begin on or about

September 30, 1999 and will be made for a 12-month budget period within a project period of up to three years. The funding estimate 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.

Funding Preferences

Although applications for new studies are encouraged, funding preference will be given to the competing continuation application over applications for programs not already receiving support under the existing program. The current awardee has implemented vaccine research that requires continued support to become fully developed and to realize the benefits of continued vaccine development (see Background Information Attachment II).

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under 1., below, and CDC shall be responsible for conducting activities under 2., below:

1. Recipient Activities
 - a. Develop study design to accomplish the research goals described above.
 - b. Perform all inoculations of research animals. Maintain records of clinical observations and obtain samples for laboratory analysis.
 - c. Perform laboratory analysis of samples obtained from study animals.
 - d. Provide routine veterinary care, housing and other support for rhesus macaques to be used in experiments. Comply fully with PHS policies regarding research on animal subjects.
 - e. Maintain sufficient numbers of rhesus macaques so that experiments can be completed within an appropriate amount of time.
 - f. Develop experimental measles vaccines and evaluate them in the animal model.
 - g. Analyze data and prepare manuscripts describing results of research investigations.
2. CDC Activities
 - a. Provide technical assistance and advice for design and conduct of the research.
 - b. Provide assistance in development of various preparations of measles virus antigens, recombinant viruses, rescued viruses or cDNA clones for use as experimental vaccines.
 - c. Provide specialty reagents such as monoclonal and polyclonal

antiserum and PCR primers as necessary.

- d. Assist in conducting specialized analysis of samples obtained from test animals. These may include special serological or immunological assays, as well as assays to detect and measure measles virus or measles virus RNA in various tissue samples. Assist with genetic characterization of viruses used in the study.
- e. Assist in data analysis and presentation.

E. Application Content

Use the information in the 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 them in laying out your program plan. The narrative should be no more than 10 double-spaced pages, printed on one side, with one inch margins, and unreduced font.

F. Submission and Deadline

Application

Submit the original and two copies of PHS-5161-1 (OMB Number 0937-0189). Forms are in the application kit. On or before June 2, 1999, submit the application to: Gladys Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99066, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341-4146.

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

1. Received on or before the deadline date; or
2. Sent on or before the deadline date and received in time for orderly processing. (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 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 criteria by an independent review group appointed by CDC (100 total points):

1. Background and Need (10 total points)

Extent to which applicant demonstrates a clear understanding of the purpose and objectives of this proposed cooperative agreement.

2. Capacity (45 total points)
 - a. Extent to which applicant describes adequate resources and facilities for conducting the project. Extent to which facilities for the safe handling of infectious agents are available. (5 points)
 - b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed in this cooperative agreement as evidenced by curriculum vitae, publications, etc. Extent to which the applicant demonstrates experience with virology, particularly the virology of measles virus. (10 points)
 - c. Extent to which applicant demonstrates experience with viral pathogenesis and immunology in rhesus macaques or other primate system. Extent to which the applicant can demonstrate previous or ongoing experience with measles infections of primates. Extent to which the applicant can produce a measles infection that is similar to measles infections in humans in rhesus macaques following intranasal inoculation. (30 points)
3. Objectives and Technical Approach (45 total points)
 - a. Extent to which applicant describes objectives of the proposed project which are consistent with the purpose and program requirements of this cooperative agreement and which are measurable and time-phased. (5 points)
 - b. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives (also see Attachment III). (20 points)
 - c. Extent to which applicant provides a detailed plan for evaluating study results and for evaluating progress towards achieving project objectives. (20 points)
4. Budget (Not Scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.
5. Animal Subjects (Not Scored)

Extent to which the application adequately address the

requirements of Public Health Policy on Humane Care and Use of Laboratory Animals.

H. Other Requirements

Technical Reporting Requirements Provide CDC with original plus two copies of:

1. progress reports (annual);
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

- AR-3 Animal Subjects Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2000
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act Sections 301(a)[42 U.S.C. 241(a)], 311 [42 U.S.C. 243], and 317(k) (1) and (2)[42 U.S.C. 247b(k) (1) and (2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

To Receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. Please refer to Program Announcement 99066. You will receive a complete program description, information on application procedures, an application package. If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, telephone (770) 488-2753, e-mail address, gcg4@cdc.gov.

See also the CDC home page on the Internet: <http://www.cdc.gov>.

For program technical assistance, contact Paul A. Rota, Ph.D., Supervisory Microbiologist, Measles Section, National Center For Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop C-22, Atlanta, GA 30333, telephone (404) 639-3308, fax (404) 639-4187, e-mail address, par1@cdc.gov.

Dated: April 1, 1999.

John L. Williams,

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

[FR Doc. 99-8567 Filed 4-6-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 29, 1999, from 9 a.m. to 5:30 p.m., and on April 30, 1999, from 8:30 a.m. to 4 p.m.

Location: National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211, or Lauren W. Parcover (HFD-21), 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 29, 1999, the committee will discuss new drug application (NDA) 19-865/S-007, Betapace® (sotalol), Berlex Laboratories, Inc., for prevention of the recurrence of chronic or paroxysmal symptomatic

atrial fibrillation/atrial flutter. On April 30, 1999, the committee will discuss the interpretation of antiarrhythmic trials in patients with implanted ventricular defibrillators.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 21, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 21, 1999, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 26, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99-8500 Filed 4-6-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Abuse Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Drug Abuse Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 20, 1999, from 8:30 a.m. to 4 p.m.

Location: Center for Drug Evaluation and Research/Advisory Committee Conference Room, 5630 Fishers Lane, Rockville, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20057, 301-827-7001, or