Dated: May 19, 1995.

Joseph R. Carter,

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

[FR Doc. 95–12834 Filed 5–24–95; 8:45 am]

BILLING CODE 4163–18–P

[Announcement 519]

Prevention of the Complications of Hemophilia

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for a cooperative agreement program to conduct a trial of primary prophylaxis therapy for the prevention of joint disease and/or inhibitor formation in children with hemophilia.

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 to the priority area of Diabetes and Chronic Disabling Conditions. (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

Authority

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act, as amended [42 U.S.C. 241(a) and 247b(k)(2)]. Applicable program regulations are found in 42 CFR Part 51b—Project Grants for Preventive Health Services.

Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote 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

Because of the low prevalence of hemophilia, competition is limited to hemophilia treatment centers (HTCs) that routinely access and administer comprehensive health care to sufficient numbers of previously untreated patients with severe hemophilia each year. Since HTCs are the only health care facilities administering to the numbers of hemophiliacs required for this study, assistance will be provided only to hemophilia treatment centers.

Availability of Funds

Approximately $500,000 is available in FY 1995 to fund up to two awards. It is expected that the award will begin on or about September 30, 1995, and will be made for a 12-month budget period within 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 programmatic progress and the availability of funds.

Purpose

The purpose of this hemophilia cooperative agreement program is to assist recipients in the implementation of and analysis of data from a randomized, controlled trial of primary prophylaxis in previously untreated patients with severe hemophilia A and no demonstrable factor VIII inhibitors. Cost and efficacy of early intervention should be determined in the treatment group and should be compared to similar data from appropriately treated, control subjects. In addition to objective measures of joint function and mobility, the cumulative risk of factor VIII inhibitor development should be determined for each treatment group and total costs and complication rates ascertained. Molecular characterization of factor VIII defects and detailed molecular HLA typing should be determined for all subjects in an effort to predict which subjects will develop inhibitors.

Program Requirements

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

A. Recipient Activities

1. Develop standardized study protocols, data collection instruments, interview questionnaires, progress report forms, and amend previous protocols with new activities or procedures incorporating all changes agreed to at assistance meetings.

2. Train study coordinators and medical personnel in methods of data collection and patient assessment in the use of standard data abstraction instruments, in techniques of reviewing medical records, in interviewing patients, and in other methods of data collection as appropriate and provided for in the study protocols. It is the responsibility of the recipient to ensure uniform training of study personnel at all data collection sites and to ensure that the data is collected in a uniform manner at all locations.

3. Develop appropriate management and evaluation systems to ensure that study personnel use data collection and interview instruments according to standard study protocols.

4. Collect and edit all data from all sites, including cost effectiveness data.

5. Obtain and transmit to CDC sufficient clinical specimens for specialized laboratory analysis and genetic testing, including whole blood, plasma, cell pellets or joint tissue/fluid, to meet the requirements of the study.

6. Publish the results of the study using a writing committee to determine the inclusion and order of authors on all publications.

B. CDC Activities

1. Provide consultation, and scientific and technical assistance in planning and implementing the study protocol. This assistance will include the development of standard study protocols, data abstraction instruments, interview questionnaires, consent and progress report forms.

2. Participate in the planning, coordination, and facilitation of initial and periodic meetings with recipients to exchange operational experiences, and to provide consultation and assistance in the modification of standard study protocols as needed.

3. Provide the required software and technical assistance in statistical and epidemiologic methods to conduct data analysis.

4. The coagulation research laboratory at CDC will be responsible for confirmation of factor VIII inhibitor levels and will serve as the central reference laboratory for molecular analysis of all study participants. CDC will be responsible for epitope typing of all inhibitors and other specialized immunological/genetic testing.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria: (Total 100 points)

A. Capacity

1. The capacity of the applicant to accrue a minimum total of 40 boys with severe factor VIII (<1%) who are 30 months old or less without a history of joint hemorrhage from multiple HTCs to each treatment arm of the protocol. Each participating HTC must be able to enroll a minimum of 5 previously untreated patients who meet the above criteria. (20 points)

2. The capacity to accrue and maintain patients on trials will be measured by (a) the number of patients

eligible for randomization into the trial that are seen annually at each HTC, (b) the number of patients entered and successfully followed in previous similar trials and (c) the publication of the results of other such trials in peer reviewed journals. Such publications should demonstrate that the applicant is capable of enrolling and following young hemophiliacs in a clinical trial. (20 points)

3. Qualifications of proposed staff to meet stated objectives and goals, and the availability of facilities to be used during the project period. (10 points)

B. Goals and Objectives

The extent to which the applicant's proposed goals and objectives meet the required activities specified under section A. ''Recipient Activities'' of this announcement, and that are measurable, specific, time-phased, and realistic. (10 points)

C. Methods and Activities

1. The quality of the applicant's plan for conducting program activities and the extent to which the clinical trial design proposed is: (a) appropriate to accomplish stated goals and objectives; (b) acceptable to the needs of the patient population (e.g., likely to produce compliance); (c) feasible within programmatic and fiscal restrictions. (30 points)

2. The recipient should demonstrate a basic knowledge of the methods of randomized, clinical trials and describe how they will implement a standardized protocol at various HTCs; (a) develop standardized progress report forms; (b) collect, edit, and transmit appropriate data to the CDC. (10 points)

D. Budget

The extent to which the budget is reasonable and consistent with the intended use of the cooperative agreement funds. (not scored)

Funding Priorities

In order to maximize the probability of developing meaningful conclusions from this randomized trial in the shortest possible time, funding priorities will take into consideration the ability of the HTC (including geographical representation of all participating HTCs) to accrue up to 40 previously untreated hemophilia patients in each treatment arm of the protocol.

Interested persons are invited to comment on the proposed funding priorities. All comments received on or before June 26, 1995 will be considered before the final funding priorities are established.

Written comments should be addressed 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–18, Atlanta, Georgia 30305.

Executive Order 12372 Review

This program is not subject to Executive Order 12372 review.

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, Centers for Disease Control and Prevention (CDC)—Investigations and Technical Assistance.

Other Requirements

Paperwork Reduction Act

Projects that involve collection of information from 10 or more individuals and funded by the cooperative agreements 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 which 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 evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit.

All information obtained in connection with this prevention trial shall not, without such individual's consent, be disclosed except as may be necessary to provide services to him or her or as may be required by a law of a State or political subdivision of a State. Information derived from any such program may be disclosed: (1) in summary, statistical, or other form, or (2) for clinical or research proposed, but only if the identity of the individuals under such program is not disclosed.

Application Submission and Deadline

The original and five copies of the application PHS Form 398 (OMB Number 0925–0001) 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, Mailstop E–18, Atlanta, Georgia 30305, on or before July 7, 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 acceptable as 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 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 Locke Thompson, 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, Mailstop E–18, Atlanta, Georgia 30305, telephone (404) 842–6595. Programmatic technical assistance may be obtained from Bruce Evatt, M.D., Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–64, Atlanta, Georgia 30333, telephone (404) 639–3925.

Please refer to Announcement Number 519 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 19, 1995.

Joseph R. Carter,

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

[FR Doc. 95–12835 Filed 5–24–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

MEETING: The following advisory committee meeting is announced:

Fertility and Maternal Health Drugs Advisory Committee With Generic Drugs and Endocrinologic and Metabolic Drugs Advisory Committee Representation

Date, time, and place. July 27 and 28, 1995, 9 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, July 27, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, July 28, 1995, 9 a.m. to 5 p.m.; Philip A. Corfman, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3510, or Kimberly Topper, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Fertility and Maternal Health Drugs Advisory Committee, code 12537.

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 the practice of obstetrics and gynecology.

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 July 7, 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. The committee will discuss the necessary components of conjugated estrogens as they relate to clinical efficacy of conjugated estrogens and other estrogen replacement drug products for approved indications. Copies of the draft agenda will be available June 1, 1995, from CDER Executive Secretariat Staff (HFD–8), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. The final agenda will be available at the meeting.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.