have appropriate training and experience in the field of autism, other developmental disabilities, and surveillance activities, as evidenced by publications, presentations, or other materials that document prior work. Demonstration of the ability to provide adequate facilities and other necessary resources to carry out all proposed activities.

5. Budget (Not Scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the stated objectives and proposed activities.

6. Human Subjects Requirements (Not Scored)

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

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual reports, no more than 30 days after the end of the report period;
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 the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

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

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, [42 U.S.C. sections 241 and 247b, as amended]. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other documents may be downloaded through the CDC homepage on the Internet at http://www.cdc.gov (click on funding).

Please refer to Program Announcement 00107 when you request information. For business management technical assistance, please contact: Mattie B. Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770/488–2718, Email address: mij3@cdc.gov.

For program technical assistance, contact: Tom Horne, Principal Management Officer, Developmental Disabilities Branch, National Center for Environmental Health, Centers for Disease Control and Prevention (F–15), 4770 Buford Hwy, NE, Atlanta, GA 30341, Telephone: 770/488–7364, Email address: tjh1@cdc.gov.

Dated: April 28, 2000.

John L. Williams,

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

[FR Doc. 00–11092 Filed 5–3–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00103]

C. Everett Koop Community Health Information Center—A National Model for Physician-Based Community Health Information Centers; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a grant program entitled ''C. Everett Koop Community Health Information Center—A National Model for Physician-based Community Health Information Centers.''

CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010'' a national activity to reduce morbidity and mortality and improve the quality of life. This program addresses the ''Healthy People 2010'' focus area of Health Communication.

For the conference copy of ''Healthy People 2010,'' visit the internet site: http://www.health.gov/healthypeople.

The purpose of the program is to strengthen the C. Everett Koop Community Health Information Center (CHIC) by (1) conducting a follow-up evaluation of CHIC as an effective model for other community health information centers, (2) disseminating the results of the evaluation to professional medical societies nationwide, and (3) conducting a final assessment of the dissemination and use of the model in other communities.

B. Eligible Applicants

Assistance will be provided only to the C. Everett Koop Community Health Information Center, Philadelphia College of Physicians, Philadelphia, PA. No other applications are solicited. The sole source justification is based on congressional language in fiscal year 2000 CDC Appropriation, which provides earmarked funding for the C. Everett Koop Community Health Information Center in Philadelphia, PA.

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 $200,000 is available in FY 2000 to fund the C. Everett Koop Community Health Information Center. It is expected that the award will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of three years. Funding estimates 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.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the following:

1. Strengthening the CHIC program by fully implementing the recommendations of the 1999 evaluation related to (a) marketing, promotion, and visibility, (b) resources, and (c) accessibility (See attachment I for recommendations).
2. Encouraging community involvement by developing a network of partners in providing current, complete, and comprehensive health information, and in increasing awareness of the availability of information resources.
3. After the recommendations have been fully implemented, developing a

plan for a follow-up evaluation of the CHIC program.

4. Establishing an advisory committee to plan for the dissemination of the evaluation results nationwide.

5. Analyzing data, implementing recommendations from the follow-up evaluation, disseminating the evaluation results to similar medical societies nationwide, and a followup assessment of the dissemination of and use of the model in other communities in years two and three.

E. Application Content

Application

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 20 double-spaced pages, printed on one side, with one inch margins, and unreduced font.

F. Submission and Deadline

Submit the original and two copies of the application PHS Form 398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available at the following Internet address: www.cdc.gov/. Forms, or in the application kit. On or before June 1, 2000, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: The application shall be considered as meeting the deadline above if it is either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date.

(Applicant must 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 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

The application will be evaluated by an objective review panel based on the following criteria:

Background (10 Points)

The extent to which the applicant demonstrates an understanding of the current literature and theories relevant to the proposed activities.

Program Plan (40 Points)

1. The extent to which the overall program plan has clear objectives that are specific, measurable, and realistic. (10 points)

2. The extent to which the proposed program activities are well-specified, achievable, time-phased, and consistent with the proposed objectives. (10 points)

3. The extent to which the proposed research methods (*e.g.,* data collection, outcome measures, data analyses, etc.) are clear and appropriate, have scientific merit, and are consistent with proposed objectives and activities. (10 points)

4. The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic and racial groups in the proposed research. 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. (10 points).

Evaluation Plan (20 Points)

The quality of the plan to evaluate the overall project as well as specific program activities in regard to progress, efficacy, and cost benefits.

Collaborations (20 Points)

1. The extent to which the applicant has described a plan for establishing and gathering input from an advisory committee that includes experts with expertise critical to the success of the project. (10 points)

2. The extent to which the applicant has described a plan for establishing collaborative relationships with appropriate organizations, individuals, federal, state, and local health and education agencies to implement and evaluate the proposed activities. (10 points)

Management and Staffing Plan (10 Points)

The extent to which the applicant demonstrates the scientific expertise and capacity to carry out the program objectives and specific project plan.

Budget (Not Scored)

The extent to which the budget and justification are consistent with program objectives and purpose.

Human Subjects (Not Scored)

If the proposed project involves human subjects, whether or not exempt from the Department of Health and Human Services (DHHS) regulations, the extent to which adequate procedures are described for the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports (annual);

2. Financial status report, not 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 the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

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

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–8 Public Health System Reporting Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317(k)(2) and 1706 [42 U.S.C. 241(a), 247(k)(2) and 300u–5] of the Public Health Services Act, as amended. The Catalog of Federal Domestic Assistance number is 93.135.

J. Where To Obtain Additional Information

This announcement and other CDC program announcements can be found on the CDC home page Internet—http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To obtain additional information contact: Cynthia Collins, Grants Management Specialist, Grants

Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (Centers for Disease Control), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone (770) 488–2757, E-mail address:coc9@cdc.gov.

For program technical assistance, contact: Elijah West, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–44, Atlanta, GA 30341–3724, Telephone 404–488–5549, E-mail address:ejw1@cdc.gov.

Dated: April 28, 2000.

Henry S. Cassell, III,

Acting Director, Procurement and Grants Office, Center for Disease Control And Prevention (CDC).

[FR Doc. 00–11094 Filed 5–3–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1220]

The Future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH); Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''The Future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use'' to solicit information and receive comments on the future of the ICH. The purpose of the meeting is to solicit public input prior to the next Steering Committee meeting in Brussels, Belgium, July 2000, at which discussion of the future of the ICH will be continued.

DATES: The public meeting will be held on May 16, 2000, from 10 a.m. to 2 p.m. Registration must be received by May 9, 2000. Written and electronic comments regarding the public meeting must be submitted by May 20, 2000.

ADDRESSES: The public meeting will be held in the Center for Drug Evaluation and Research, Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Written submissions must be sent to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic submissions must be sent to the Dockets Management Branch at http://www.fda.gov/scripts/oc/dockets/comments/commentsmain.cfm.

FOR FURTHER INFORMATION CONTACT: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6801, or e-mail: Topperk@cder.fda.gov.

Registration: There is no registration fee for this public meeting, but registration by May 9, 2000, is required. Participation is limited to the first 140 registrants due to limited space. FDA employees are required to register to attend the meeting. Interested persons may register with the contact person via e-mail at: topperk@cder.fda.gov or fax 301–827–6801 and provide the following information: Name, affiliation, address, phone, fax, and e-mail address. Interested persons may also register by mail with the contact person (address above).

SUPPLEMENTARY INFORMATION:

I. Background

The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization among the following three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Therapeutics Products Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at http://www.ifpma.org/ich1.html.

The ICH will present the Common Technical Document and other significant achievements at the ICH 5 Conference in San Diego in November 2000. In preparing for this meeting, the ICH Steering Committee is evaluating the future direction for the ICH, including structure, processes, work program, and global cooperation. FDA is soliciting public input at this time to assist the agency in these deliberations.

II. Issues To Be Discussed at the Public Meeting

The issues to be discussed include the following: (1) Administrative and technical issues, (2) future participation, (3) global cooperation, and (4) new topic areas.

Interested persons may present data, information, or views, orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by May 9, 2000, and submit: A brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.