collaborate on specific community concerns, and seeks resolution of those concerns through a formalized relationship documented by written memoranda of understanding/agreement signed by individuals with the authority to represent the organizations (e.g., president, chief executive officer, executive director).

Minority Community-Based Organization—Public and private nonprofit community-based minority organization or a local affiliate of a national minority organization that has: a governing board composed of 51 percent or more racial/ethnic minority members, a significant number of minorities employed in key program positions, and an established record of service to a racial/ethnic minority community.

Minority Populations—American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, and Native Hawaiian or Other Pacific Islander. (Revision to the Standards for the Classification of Federal Data on Race and Ethnicity, **Federal Register**, Vol. 62, No. 210, pg. 58782, October 30, 1997.)

Reporting and Other Requirements

General Reporting Requirements

A successful applicant under this notice will submit: (1) progress reports; (2) an annual Financial Status Report; and (3) a final progress report and Financial Status Report in the format established by the Office of Minority Health, in accordance with provisions of the general regulations which apply under CFR 74.50–74.52.

Provision of Smoke-Free Workplace and Non-Use of Tobacco Products by Recipients of PHS Grants

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Public Health System Reporting Requirements

This program is subject to Public Health Systems Reporting Requirements. Under these requirements, a community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit, no later than the Federal due date for receipt of the application, the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted: (a) a copy of the face page of the application (SF 424), and (b) a summary of the project (PHSIS), not to exceed one page, which provides: (1) a description of the population to be served, (2) a summary of the services to be provided, and (3) a description of the coordination planned with the appropriate State or local health agencies. Copies of the letters forwarding the PHSIS to these authorities must be contained in the application materials submitted to the Office of Minority Health.

State Reviews

This program is subject to the requirements of Executive Order 12372 which allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application kit to be made available under this notice will contain a listing of States which have chosen to set up a review system and will include a State Single Point of Contact (SPOC) in the State for review. Applicants (other than federally recognized Indian tribes) should contact their SPOCs 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. The due date for State process recommendations is 60 days after the application deadline established by the Office of Minority Health's Grants Management Officer.

The Office of Minority Health does not guarantee that it will accommodate or explain its responses to State process recommendations received after that date. (See ''Intergovernmental Review of Federal Programs'' Executive Order 12372 and 45 CFR Part 100 for a description of the review process and requirements).

Authority: This program is authorized under section 1707(e)(1) of the Public Health Service Act, as amended by Pub. L. 105–392.

OMB Catalog of Federal Domestic Assistance: The OMB Catalog of Federal Domestic Assistance number for this program is pending.

Dated: June 17, 1999.

Nathan Stinson, Jr.,

Acting Deputy Assistant Secretary for Minority Health.

[FR Doc. 99–16069 Filed 6–23–99; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99156]

Cooperative Agreement With a National Organization for Promoting Health, Preventing Disease and Disability, and Managing Chronic Disease in the Workplace; 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 with a national organization for promoting health, preventing disease and disability, and managing chronic disease in the workplace. This announcement relates to all areas of ''Healthy People 2000.'' The purpose of this program is to promote the attainment of the objectives outlined in ''Healthy People 2000'' through the translation of public health principles and practices into easily interpretable and actionable information for the workplace.

B. Eligible Applicants

Applications will be accepted from national, nonprofit organizations who provide documented proof of meeting the following criteria in the ''Eligibility'' section of the application:

1. Be an established tax-exempt organization (i.e., a non-governmental, tax exempt corporation or association whose net earnings in no way accrue to the benefit of private shareholders or individuals). Tax-exempt status may be confirmed by providing a copy of the relevant pages from the Internal Revenue Service's (IRS) most recent list of 501(c)(3)or(6) tax exempt organizations or a copy of the current IRS Determination Letter. Proof of tax exempt status must be provided with the application.

2. Have a membership composed primarily of large private employers with multi-state and/or national operations and sales.

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 $350,000 is available in FY 1999 for 1–2 awards. It is expected that the average award will be $175,000, ranging from $75,000 to $275,000. It is expected that awards will begin on or about September 30, 1999, for a 12-month budget period within a project period of up to 3 years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by the successful completion of required activities and reports, and by the availability of funds.

D. Program Requirements

In conducting activities to achieve the purposes of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities under 2. CDC Activities.

1. Recipient Activities

a. Develop and implement a needs assessment of members in the areas of health promotion, disease and disability prevention, chronic disease management, wellness and health screening programs, health care quality assessment and improvement, health benefits purchasing, and community outreach.

b. Disseminate information to members concerning health and health-related issues through various methods, not necessarily limited to conferences, meetings, seminars, symposia, and publications.

c. Facilitate communication, information sharing, collaboration, and recognition of achievements on health and health-related issues and activities among members.

d. Work with members to promote broad public and population health objectives.

e. Develop a model(s) for partnerships for health in the workplace.

2. CDC Activities

a. Provide technical assistance and monitor the progress of all aspects of this cooperative agreement.

b. Provide up-to-date scientific information.

E. Application Content

Use the information in the Purpose, Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Applications will be evaluated on the criteria listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 25 double-spaced pages, printed on one side, with one-inch margins and 12-point font.

1. Organizational Profile (Maximum 7 Pages)

a. Provide a narrative on the applicant organization, including: Background information, evidence of relevant experience, and a clear understanding of this announcement's purpose. Provide evidence of an organizational structure and mission that can meet the requirements of this program.

b. Provide a membership listing and an estimate of members' combined total workforce.

c. Include details of past experiences working with members on health and health-related issues.

d. Profile qualified personnel who are available to work under this agreement. Include a global organizational chart which also demonstrates the geographic location(s) and organizational positions of all anticipated personnel.

2. Program Plan (Maximum 18 Pages)

a. Provide clear and concise descriptions of proposed recipient activities; demonstrating your understanding of public health principles, the intent of this announcement, and your members' needs. Include some preliminary ideas on members' needs (in the areas of health promotion, disease and disability prevention, chronic disease management, wellness and health screening programs, health care quality assessment and improvement, health benefits purchasing, and community outreach) and how they relate to this announcement.

b. Include goals and measurable objectives that are specific, time-framed and relevant to the intent of this announcement. Detail the potential benefits of the proposed objectives.

c. Provide an action plan, including a timeline of activities and personnel responsible for implementing each segment of the plan.

d. Include an evaluation plan which encompasses both qualitative and quantitative measures for the achievement of program objectives, as well as a mechanism for mid-course correction when those objectives are not being met.

e. Provide a plan for sharing findings/results indicating when, to whom, and in what format.

f. Provide a plan for obtaining additional resources from non-federal sources to supplement program activities and ensure their continuation after the end of the project period.

3. Budget Information

Provide a detailed budget with justification. The budget proposal should be consistent with the purpose, program requirements, and program plan presented.

F. Submission and Deadline

Submit the original and two copies of PHS–5161–1 (OMB Number 0937–0189). Forms are in the application kit.

On or before August 16, 1999, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

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 orderly processing. (Applicants must request a legibly dated U.S. Postal Service postmark or 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.

1. Organizational Profile (15 Points)

The extent to which the applicant's existing organizational structure, mission, goals, objectives, activities, functions and membership composition are consistent with the purpose of this Program Announcement.

2. Capability (25 Points)

The extent to which the applicant appears likely to succeed in implementing the proposed activities as measured by relevant past history, a sound management structure and staff qualifications—including the appropriateness of proposed roles, responsibilities and job descriptions.

3. Program Plan (40 Points)

The extent to which the applicant's program plan meets the required activities specified under ''Recipient Activities'' in this announcement; and are measurable, specific, time-framed and realistic.

4. Evaluation (20 Points)

The extent to which the applicant has developed mechanisms for evaluating and reevaluating progress toward stated goals and objectives which include feedback from its membership. The extent to which the applicant builds in the capacity for mid-course correction(s) based on those evaluations.

5. Budget (Not Scored)

The extent to which the budget is reasonable in the amount(s) requested, justified by the application content, and consistent with the intentions of this announcement.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Annual progress reports;
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 package.

AR–9 Paperwork Reduction Act 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 sections 301 and 317(k)(2) of the Public Health Service Act [42 U.S.C. 241 and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

To download this and other CDC Program Announcements, you can go the CDC home page *www.cdc.gov* and click on ''funding''.

If you do not have Internet access 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 99156 when you request information. Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99156, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341, Telephone (770) 488–2717, Email address jcw6@cdc.gov.

For program technical assistance, contact:

Kenneth A. Schachter, M.D., M.B.A., Medical Director, Epidemiology Program Office, Office of HealthCare Partnerships, Centers for Disease Control and Prevention (CDC), Telephone 404/639–4449, Email address kbs3@cdc.gov
and
Priscilla B. Holman, M.S. Ed., Health Communication Corporate Liaison, Office of Program Planning and Evaluation, Centers for Disease Control and Prevention (CDC), Telephone: 404/639–1929, E-mail: pbh2@cdc.gov

Dated: June 18, 1999.

John L. Williams,

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

[FR Doc. 99–16065 Filed 6–23–99; 8:45 am]

BILLING CODE 1463–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1718]

Draft Guidance for Industry on Monoclonal Antibodies Used as Reagents in Drug Manufacturing; 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 ''Monoclonal Antibodies Used as Reagents in Drug Manufacturing.'' This draft guidance provides recommendations to sponsors and applicants on the information that should be included in investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), biologics license applications (BLA's), and supplements to these applications when monoclonal antibodies are used as reagents in the manufacture of drug substances and drug products that are regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

DATES: Written comments on the draft guidance document may be submitted by September 22, 1999. 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 for industry 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 requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Eugenia M. Nashed, Office of New Drug Chemistry (HFD–570), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050, or

Kurt A. Brorson, Office of Therapeutics Research and Review (HFM–561), Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892–0029, 301–827–0661.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Monoclonal Antibodies Used as Reagents in Drug Manufacturing.'' This draft guidance focuses on chemistry, manufacturing, and control issues relating to the use of monoclonal antibodies as reagents in drug substance and drug product manufacture that should be addressed in IND's, NDA's, ANDA's, BLA's, and supplements to these applications.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on monoclonal antibodies used as reagents. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An