

Definitions

For purposes of this grant announcement, the following definitions are provided:

AIDS Service Organization (ASO): A health association, support agency, or other service activity involved in the prevention and treatment of AIDS. (HIV/AIDS Treatment Information Service's Glossary of HIV/AIDS-Related Terms, March 1997.)

Community-Based Organization: A private nonprofit organization that is representative of communities or significant segments of communities, and where the control and decision-making powers are located at the community level.

Community-Based Minority-Serving Organization: A community-based organization that has a history of service to racial/ethnic minority populations. (See definition of Minority Population below.)

Community Coalition: At least three (3) discrete organizations and institutions in a community which collaborate on specific community concerns, and seek 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).

Cultural Competency: A set of behaviors, attitudes, and policies that enable a system, agency, and/or individual to function effectively with culturally diverse clients and communities. (Randall-David, E., 1989)

Intervention: A combination of services designed to alter or modify a condition or outcome, or to change behavior to reduce the likelihood of a preventable health problem occurring or progressing further. Services include:

- Clinical preventive services (e.g., blood pressure screening)
- Environmental modifications
- Educational activities
- Coordinated networking activities among health and human service related programs

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.)

Risk Factor: The environmental and behavioral influences capable of causing ill health with or without predisposition.

Sociocultural Barriers: Policies, practices, behaviors and beliefs that create obstacles to health care access and service delivery (e.g., cultural differences between individuals and institutions, cultural differences of beliefs about health and illness, customs and lifestyles, cultural differences in languages or nonverbal communication styles).

Dated: June 20, 2002.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Availability of Funds for Grants for the State and Territorial Minority HIV/AIDS Demonstration Grant Program

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Minority Health.

ACTION: Notice.

SUMMARY: The purposes of this Fiscal Year (FY) 2002 State and Territorial Minority HIV/AIDS Demonstration Program are to:

1. Assist in the identification of needs within the state for HIV/AIDS prevention and services among minority populations (see definition of Minority Populations) by collection, analysis, and/or tracking of existing data on surveillance and existing providers of HIV services for minority communities;
2. Facilitate the linkage of community-based minority-serving organizations with other state and local recipients of federal funds for HIV/AIDS to develop greater resource capacity and interventions in the identified areas of need; and
3. Assist in coordinating Federal resources coming into high need, minority communities including identifying the different programs and facilitating access to federal technical assistance available to community-based minority-serving organizations.

Authority: This program is authorized under section 1707(e)(1) of the Public Health Service Act (PHS), as amended.

This program is intended to demonstrate that the involvement of state and territorial offices of minority health in coordinating a statewide response to the HIV/AIDS crisis in minority communities can have a greater impact on the communities'

understanding of the disease, and the coordination of prevention and treatment services for minority populations, than agencies/organizations working independently.

Project outcomes must include any or all of the following:

- Reduction in high-risk behaviors by increasing the capacity of community-based minority-serving organizations to work directly with hardly reached minority populations (e.g., youth, women at risk, men having sex with men, homeless persons, injection drug users, mentally ill persons, incarcerated persons).

- Improved capacity of states to identify gaps in resources in areas of need to address the HIV/AIDS epidemic.

- Increased capacity of community-based minority-serving organizations to identify, apply for, and receive funding for support of activities to address identified gaps.

- Increased counseling and testing services by increasing the capacity of community-based minority-serving organizations to work directly with hardly reached minority populations (e.g., youth, women at risk, men having sex with men, homeless persons, injection drug users, mentally ill persons, incarcerated persons).

ADDRESSES: For this grant, applicants must use form PHS 5161-1 (Revised July 2000 and approved by OMB under Control Number 0348-0043). Applicants are advised to pay close attention to the specific program guidelines and general instructions provided in the application kit. To get an application kit, write to: Ms. Chanee Jackson, OMH Grants Management Center, c/o Health Management Resources, Inc., 8401 Corporate Drive, Suite 400, Landover, MD 20785, e-mail grantrequests@healthman.com, fax (301) 429-2315; or call Chanee Jackson at (301) 429-2300. Send the original and 2 copies of the complete grant application to Ms. Chanee Jackson at the same address.

DATES: To receive consideration, grant applications must be postmarked by the OMH Grants Management Center by 5 p.m. EDT on July 25, 2002. Applications postmarked after the exact date and time specified for receipt will not be accepted. Applications submitted by facsimile transmission (FAX) or any other electronic format will not be accepted. Applications which do not meet the deadline will be returned to the applicant unread.

FOR FURTHER INFORMATION CONTACT: Ms. Karen Campbell, Grants Management Officer, for technical assistance on budget and business aspects of the

application. She may be contacted at the Office of Minority Health, Rockwall II Building, Suite 1000, 5515 Security Lane, Rockville, MD 20852; or by calling (301) 594-0758. For questions on the program and assistance in preparing the grant proposal, contact: Ms. Cynthia H. Amis, Director, Division of Program Operations, at the same address; or by calling (301) 594-0769.

For additional assistance, contact OMH Regional Minority Health Consultants listed in the grant application kit. For health information, call the OMH Resource Center at 1-800-444-6472.

SUPPLEMENTARY INFORMATION: OMB Catalog of Federal Domestic Assistance: The OMB Catalog of Federal Domestic Assistance Number for this program is 93.006.

Availability of Funds: About \$2.5 million is expected to be available for award in FY 2002. It is expected that 17 to 25 awards will be made. Support may be requested for a total project period not to exceed 3 years.

Those applicants funded through the competitive process:

- Are to begin their service demonstration programs on September 30, 2002.
- Will receive an award up to \$150,000 total costs (direct and indirect) for a 12-month period.
- Will be able to apply for a noncompeting continuation award up to \$150,000 (direct and indirect) for each of two additional years. After year 1, funding will be based on:
 - The amount of money available; and
 - Success or progress in meeting project objectives.

Note: For the noncompeting continuation awards, grantees must submit continuation applications, written reports, and continue to meet the established program guidelines.

Eligible Applicants: Eligibility is limited to state and territorial¹ offices of minority health or, for those states and/or territories that do not have an established office of minority health, a state or territorial minority health entity located within a state or territorial department of health which functions in the capacity of an office of minority health. (See definitions in this announcement.)

Documentation to verify official status as a state or territorial office of minority health or as a state or territorial minority health entity must be submitted.

A letter of support and commitment to the proposed demonstration project

from an authorizing official such as the state or territorial Commissioner of Health is also required as part of the application. For the purposes of this announcement, both the established state and territorial offices of minority health and any recognized state and/or territorial minority health entity will be referred to as a state or territorial office of minority health. Each state and territory may submit only one proposal under this announcement.

Background

The Office of Minority Health's (OMH) mission is to improve the health of racial and ethnic minority populations (see definition of Minority Populations) through the development of health policies and programs that help to eliminate health disparities and gaps. OMH serves as the focal point within the Department of Health and Human Services for service demonstrations, coalition and partnership building, and related efforts to address the health needs of racial and ethnic minorities. In keeping with this mission, OMH established the State and Territorial Minority HIV/AIDS Demonstration Program in FY 1999 to assist in addressing HIV/AIDS issues facing minority communities across the United States. This program is based on the premise that a broad, state-level approach to HIV/AIDS health care promotion and prevention can be effective in reaching minority populations by both defining existing needs of prevention and treatment, and supporting strategies to address those needs. It is anticipated that this approach will strengthen existing state activities in addressing this health issue by facilitating infrastructure development or expansion of state or territorial offices of minority health to: (1) Take a lead role in identifying major areas of need in minority communities; (2) link community-based minority-serving organizations with other state and local partners in the identified areas of need; and (3) assist in coordinating federal resources coming into high need, minority communities including identifying the different programs and facilitating access to federal technical assistance available to community-based minority-serving organizations.

Effect of HIV/AIDS on Minorities

The *Census 2000 Brief*² reports the U.S. population as 281.4 million, with 36.4 million³ Blacks or African

Americans, or 12.9 percent; 35.3 million Hispanics, or 12.5 percent; approximately 12.8 million Asians/Native Hawaiians and Other Pacific Islanders, or 4.5 percent; and approximately 4 million American Indians/Alaska Natives or 1.5 percent of the total population.

HIV/AIDS remains a disproportionate threat to minorities. As of December 31, 2000, the Centers for Disease Control and Prevention (CDC) received reports of 774,467 (cumulative) cases of persons with AIDS in the U.S.⁴, of whom 38 percent were Black or African American, and 18 percent were Hispanic.

Of the 42,156 AIDS cases reported to CDC during 2000, 41,960 were adult/adolescent and 196 were children (<13 years of age). For the adult/adolescent population, 47 percent were Black or African American, and 19 percent were Hispanic. Of the 196 children reported with AIDS, 65 percent were Black non-Hispanic, and 17 percent were Hispanic.

Through December 2000, the most common exposure category reported for AIDS cases among African American and Hispanic males was men who have sex with men (37% and 42%, respectively), with the second most common exposure being injection drug use (34% and 35%, respectively).

HIV infection among U.S. women has increased significantly over the last decade, especially in communities of color. Between 1985 and 1999, the proportion of all AIDS cases reported among adult and adolescent women more than tripled, from 7 to 23 percent. African American and Hispanic women account for more than three-fourths, or 77 percent, of the AIDS cases reported among women in the U.S. Through December 2000, the most common exposure categories for AIDS cases among African American and Hispanic females were heterosexual contact (47%, Hispanic; 38%, African American) and injection drug use (41%, African American; 40%, Hispanic). Young African American and Hispanic women accounted for more than three-fourths of the HIV infections reported among females between the ages of 13 to 24, according to reports to the CDC from the 32 areas with confidential HIV reporting for adults and adolescents for all years combined through 1999.

Project Requirements

Each applicant to this demonstration grant program must:

¹ Includes all 50 states, the District of Columbia, American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Puerto Rico, Republic of Palau, and the Virgin Islands.

² U.S. Census Bureau, *The Black Population: 2000—Census 2000 Brief*, August 2001.

³ This number includes individuals who self-reported as Black, or as Black and one or more other race on the Census 2000 questionnaire.

⁴ HIV/AIDS Surveillance Report—U.S. HIV and AIDS cases reported through December 2000, Year-End Edition, Vol. 12, No. 2.

1. Address the three purposes of the program announcement:

- Assist in the identification of needs within the state for HIV/AIDS prevention and services for minority populations by collection, analysis, and/or tracking of existing data on surveillance and existing providers of HIV services for minority communities;
- Facilitate the linkage of community-based minority-serving organizations with other state and local recipients of federal funds for HIV/AIDS to develop greater resource capacity and interventions in the identified areas of need; and
- Assist in coordinating federal resources coming into high need, minority communities including identifying the different programs and facilitating access to federal technical assistance available to community-based minority-serving organizations.

2. Describe plans to establish a project advisory committee to assist the applicant in carrying out the activities specified in the project. The membership is to be comprised of five to seven individuals with the applicant serving as an ex officio member. Committee membership must include: a representative from a state office on AIDS or state HIV/AIDS coordinator, an HIV/AIDS health care provider, and a representative from an AIDS service organization serving a substantial number of people of color. Other potential members may include: a minority person living with HIV/AIDS, a representative from an HIV/AIDS community planning committee or group, an outreach worker/social worker, or a consumer/patient advocate.

Use of Grant Funds: Budgets up to \$150,000 total costs (direct and indirect) may be requested per year to cover costs of:

- Personnel
- Consultants
- Supplies
- Equipment
- Grant-related travel
- Other grant related costs

Note: All budget requests must be fully justified in terms of the proposed purpose, objectives, and activities. Funds to attend an annual OMH grantee meeting must be included in the budget.

Funds may not be used for:

- Medical treatment
- Medical supplies
- Direct services
- Fund raising activities
- Building alterations or renovations
- Construction

Review of Applications:

- Applications will be screened upon receipt. Those that are judged to be

incomplete, non-responsive, or non-conforming to the announcement will not be accepted for review and will be returned.

- Each organization may submit no more than one proposal under this announcement.
- Accepted applications will be reviewed for technical merit in accordance with PHS policies.
- Accepted applications will be evaluated by an Objective Review Committee. Committee members will be chosen for their expertise in minority health and their understanding of the health problems and related issues confronted by racial and ethnic minority populations in the United States.

Application Review Criteria: The technical review of applications will consider the following 5 generic factors.

Factor 1: Program Plan (35%)

- Appropriateness of proposed plan and specific activities for each objective
- Logic and sequencing of the planned approaches in relation to the objectives and program evaluation
- Extent to which the applicant demonstrates access to community-based minority-serving organizations

Factor 2: Evaluation (20%)

- Thoroughness, feasibility and appropriateness of the evaluation design, and data collection and analysis procedures
- Clarity of the intent and plans to document activities and their outcomes
- Potential for proposed project to impact the HIV/AIDS health disparities experienced by minority populations within the state or territory

Factor 3: Background (15%)

- Demonstrated knowledge of the impact of HIV/AIDS on the state and within minority communities
- Appropriateness of the description of the HIV/AIDS problem confronting the state and minority communities and the needs to be addressed
- Extent and documented outcome of past efforts/activities in addressing HIV/AIDS in minority communities (Currently funded State and Territorial Minority HIV/AIDS grantees [competing continuation applicants] must attach a progress report describing project accomplishments and outcomes.)

Factor 4: Objectives (15%)

- Merit of the objectives
- Relevance to the program purpose and the stated problem
- Attainability in the stated time frames

Factor 5: Management Plan (15%)

- Applicant organization's capability to manage and evaluate the project as determined by:
 - Qualifications and appropriateness of proposed staff or requirements for "to be hired" staff
 - Proposed staff level of effort
 - Composition of proposed advisory committee and defined role
- Appropriateness of defined roles including staff reporting channels and that of any proposed contractors

Award Criteria

Funding decisions will be determined by the Deputy Assistant Secretary for Minority Health, OMH and will take under consideration:

- The recommendations and ratings of the review panel
- Geographic and racial/ethnic distribution

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 OMH, in accordance with provisions of the general regulations which apply under 45 CFR part 74.51–74.52, with the exception of State and local governments to which 45 CFR part 92, subpart C reporting requirements apply.

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 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).

Healthy People 2010

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led national activity announced in January 2000 to eliminate health disparities and improve years and quality of life. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 web site: <http://www.health.gov/healthypeople>. Copies of the *Healthy People 2010: Volumes I and II* can be purchased by calling (202) 512-1800 (cost \$70 for printed version or \$19 for CDROM). Another reference is the *Healthy People 2000 Review—1998–99*.

For 1 free copy of *Healthy People 2010*, contact NCHS: The National Center for Health Statistics, Division of Data Services, 6525 Belcrest Road, Hyattsville, MD 20782-2003, or telephone (301) 458-4636; ask for HHS Publication No. (PHS) 99-1256.

This document may also be downloaded from the NCHS web site: <http://www.cdc.gov/nchs>.

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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.)

State or Territorial Offices of Minority Health: An entity established by an Executive Order, a statute or a state/

territorial health officer to improve the health of racial and ethnic populations.

State or Territorial Minority Health Entity: A unit or contact located within a state or territorial department of health that addresses the health disparities experienced by minority populations.

Dated: June 20, 2002.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

[FR Doc. 02-15985 Filed 6-24-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket NO. 87F-0153]

Dow Chemical Co.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 7B3994), filed by Dow Chemical Co. proposing that the food additive regulations be amended to provide for the safe use of hydrogen peroxide solution to sterilize vinylidene chloride-vinyl chloride copolymers in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 4, 1987 (52 FR 21122), FDA announced that a food additive petition (FAP 7B3994) had been filed by Dow Chemical CO., Midland, MI 48674. The petition proposed to amend the food additive regulation § 178.1005 *Hydrogen peroxide* solution (21 CFR 178.1005) to provide for the safe use of hydrogen peroxide solution to sterilize vinylidene chloride-vinyl chloride copolymers in contact with food. Dow Chemical Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: June 12, 2002.

George H. Pauli,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 02-15954 Filed 6-24-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective 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: Anti-Infective 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 July 10, 2002, from 8:30 a.m. to 5 p.m., and on July 11, 2002, from 8:30 a.m. to 4 p.m.

Location: Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 10, 2002, the committee will discuss the new drug application (NDA) 21-242, artesunate rectal capsules, World Health Organization, proposed for emergency treatment of acute malaria in patients who cannot take oral medication and for whom parenteral treatment is not available. On July 11, 2002, the committee will discuss clinical trial design for studies of otitis media. Since the publication of the 1998 "Draft Guidance to Industry on Acute Otitis Media—Developing Antimicrobial Drugs for Treatment" (see the FDA Internet Web site at <http://www.fda.gov/cder/guidance/>), the agency has received advice from the public and the Anti-Infective Drugs Advisory Committee on changes to clinical trial design (see transcripts from November 19, 1997; July 29 to 31, 1998; January 30, 2001; and November 7, 2001, for various antimicrobials at the FDA Internet Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>). The