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*Notice:* Due to the elevated homeland security alert announced February 7, 2003, the FCC has taken additional security precautions that will limit visitor access to the FCC headquarters building in Washington, DC. Until further notice, the Maine Avenue lobby is closed. All visitors must enter the building through the 12th Street lobby, and will require an escort at all times in the building.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

[FR Doc. 03-4158 Filed 2-14-03; 3:29 pm]

BILLING CODE 6712-01-M

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise

noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 14, 2003.

**A. Federal Reserve Bank of Atlanta** (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309-4470:

1. *F.N.B. Corporation*, Naples, Florida; to merge with Charter Banking Corp., Tampa, Florida, and thereby indirectly acquire Southern Exchange Bank, Tampa, Florida.

**B. Federal Reserve Bank of Kansas City** (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *International Brotherhood of Boilermakers, Iron Ship Builders, Blacksmiths, Forgers and Helpers*, Kansas City, Kansas; to acquire additional shares, for a total of 47.5 percent of the voting shares of Brotherhood Bancshares, Inc., and thereby indirectly acquires shares of Brotherhood Bank & Trust Company, both of Kansas City, Kansas.

Board of Governors of the Federal Reserve System, February 12, 2003.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 03-3875 Filed 2-18-03; 8:45 am]

BILLING CODE 6210-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03003]

#### HIV Community-Based Prevention Projects for the Commonwealth of Puerto Rico and the United States Virgin Islands; Notice of Availability of Funds

##### A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301(a) and 317 of the Public Health Service Act, 42 U.S.C. 241(a) and 247(b) as amended. The Catalog of Federal Domestic Assistance Number is 93.939, HIV Prevention Activities—Non-Governmental Organization Based.

##### B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year 2003 funds for a cooperative agreement program for community-based organizations (CBOs) in the Commonwealth of Puerto Rico (the Commonwealth) (Category A) and the United States Virgin Islands (USVI) (Category B) to develop and implement HIV Prevention Programs. This program addresses the "Healthy People 2010" focus area(s) of Educational and Community-Based Programs, HIV, and Sexually Transmitted Diseases.

The purpose of the program is to (1) Develop and implement effective community-based HIV prevention programs that reflect the Commonwealth's or the USVI HIV prevention priorities outlined in their comprehensive HIV prevention plan and epi profile; and

(2) Promote collaboration and coordination of HIV prevention efforts among CBOs, Health Departments, and private agencies in order to increase the number of high-risk persons who are tested for HIV infection and learn their test results.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for HIV, STD and TB Prevention: (1) Reduce the number of new HIV infections; and (2) Decrease the number of persons at high risk for acquiring or transmitting HIV infection.

All attachments referenced in this announcement are posted with the announcement on the CDC Web site, Internet address: <http://www.cdc.gov>.

##### C. Eligible Applicants

Assistance will be provided only to non-governmental organizations and faith-based organizations (tax exempt corporation or association), whose net earnings do not benefit private shareholders or individuals and who meet the following criteria:

1. Have a current tax-exempt status under Internal Revenue Service Code Section 501(c)(3) or written Statement of Good Standing and a Certificate of Incorporation from the Commonwealth State Department (Category A) or the USVI State Department (Category B).

2. Be located in the Commonwealth of Puerto Rico or the United States Virgin Islands.

3. Be able to show that you have provided HIV prevention or care services to your target population over the last two years.

4. Provide evidence that you have shared with the health department the details of your proposed program.

5. Request no more than \$175,000 in funding, including indirect costs, if applying under Category A; and no more than \$200,000, including indirect costs, if applying under Category B.

6. Not be a government or municipal agency (including a health department, school board, or public hospital), a private or public university or college, or a private hospital.

For both categories, you can apply on your own or with one or more CBOs as a coalition. The term coalition, for this announcement, means a group of organizations working together, where each organization has a clearly defined activity assigned to them from the overall program plan. All groups share program responsibilities, but the organization applying for funds must be the legal applicant and perform a substantial portion of the program activities. The lead organization must meet all of the eligibility requirements listed above.

CDC encourages applications from applicants who are representative of the minority communities served in the make up of their board of directors, key staff and management. They should also be situated in close geographic proximity to the targeted population, have a history of providing services to these communities and have documented linkages to the targeted populations.

**Note:** You may only submit one application. If you apply alone and also as part of a group, your application will not be reviewed and will be returned to you. Your organization may apply for this funding even if you are currently receiving other funding from CDC; however, you must still meet all of the eligibility requirements above.

**Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501c (4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

#### D. Funding

For fiscal year 2003, about \$1.3 million is available for awards under Category A to fund approximately eight awards and \$800,000 for Category B to fund approximately four awards. CBOs who are selected will receive funding in July 2003. The funds are to be used during a budget time frame of 12 months.

Your organization's project may be continued for a total of 5 years (*i.e.*, 2003, 2004, 2005, 2006, 2007) under this agreement. Funding at the same level after the first year is based on the amount of funds available to CDC and your success and/or progress in meeting your goals and objectives. You must

keep track of your successes by writing reports and sending them to CDC. Also, CDC staff may visit your organization to learn about your activities. When asking for the subsequent funding, you must again show CDC that you still meet the requirements stated above in the "Eligible Applicants" section.

CDC is committed to working with CBOs in these activities and to ensuring that these funds are distributed in a way that matches the geographic locations and risk behaviors where the epidemic is widespread.

#### Use of Funds

The money must be used to:

1. Target priority populations identified in the Comprehensive HIV Prevention Plan developed by the Community Planning Group.
2. Develop and implement activities and interventions described in the Comprehensive HIV Prevention Plan developed by the Community Planning Group.

The money must not be used to:

1. Give direct patient medical care, including substance abuse or medical treatment, or medications.
2. Replace or duplicate existing funding.
3. Support only administrative and managerial functions.

#### Funding Preferences

Preference will be given to applicants that:

1. Are located in or near to the targeted community they are intending to serve (Indigenous to the targeted population.)
2. Have a documented history of service to the targeted community(ies) to be served with evidence of having established systems for involving clients, and community members in identifying community needs, assets, and barriers, and in creating appropriate program response.
3. Have documented linkages to the targeted population.
4. Have documented evidence of implementing culturally and linguistically competent interventions for the targeted population.

#### Recipient Financial Participation

Matching funds are not required for this program.

#### E. Program Requirements

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

#### 1. Recipient Activities

a. Involve the target population in planning, implementing, and evaluating activities and services throughout the project period.

b. Develop or adapt existing program models that are supported by scientifically valid evidence of lowering risk behavior, encouraging abstinence, or increasing help-seeking behavior.

Examples of evidence-based models can be found: (1) In the "Compendium of Effective Behavioral Interventions", (Inventory #D235) available in CD-Rom format from the CDC National Prevention Information Network (NPIN) by calling 1-800-458-5231 or at the following Web site: <http://www.cdc.gov/hiv/pubs/hivcompendium.pdf> and (2) in the report entitled, "Positive Youth Development in the United States," commissioned by the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation and available at: <http://aspe.hhs.gov/hsp/positiveyouthdev99/index.htm>

c. Comply with the requirements described in the Review of Contents of "HIV/AIDS-Related Written Materials, Pictorials, Audiovisuals, Questioners, Survey Instruments, and Education Sessions", published in the **Federal Register** on June 15, 1992.

d. Comply with Health Department rules, regulation, protocols and procedures while implementing your counseling and testing intervention.

Your program activities should address barriers to HIV prevention. The activities could address social, health service, faith organizations and family units that can keep persons at risk from getting the services they need.

e. Conduct at least one of the interventions listed below. All of your efforts must include cultural competency, sensitivity to issues of sexual and gender identity, and developmental and linguistic appropriateness.

(1) HIV counseling, testing, and referral (CTR) Provide HIV CTR to individuals at high risk for HIV infection. If you provide these services, you must meet certain requirements and follow set guidelines. See Attachment 4 for more information.

Your program might: (a) Improve access to testing sites that will be more acceptable and accessible to the target population or, (b) Improve use of post-test counseling, referral, and follow-up.

(2) Health Education and Risk Reduction Conduct health education and risk-reduction interventions (HE/RR). These may include individual, group, or community-level interventions.

(3) Outreach Activities Conduct outreach activities to improve access to the target population. Provide face-to-face HIV prevention interactions and hand out prevention-related materials, encourage abstinence.

f. Assist high-risk clients with referrals to appropriate primary HIV prevention services, and continued prevention and care services if they are infected.

g. Assist HIV infected individuals with access to appropriate prevention interventions, care and treatment.

h. Monitor and evaluate your proposed program to assure its quality. Use approximately three to five percent of the funds awarded under this announcement for monitoring intervention activities. CDC will provide technical assistance in tracking program activities and quality.

i. If conducting counseling and testing, prepare and submit to CDC, within the first six months of funding, a quality assurance plan for your program.

j. Conduct periodic client satisfaction assessments, *e.g.*, questionnaires or focus groups.

k. Put into place training and capacity building measures and a plan to identify the training needs of your staff.

l. Work with CDC and CDC-funded capacity-building assistance programs to identify and address the capacity-building needs of your program.

m. Find and use local resources for organizational and program development, *e.g.*, the health department, community development agencies, other CBOs, local colleges and universities, locally based foundations, Service Corps of Retired Executives (a Small Business Administration program), and the local business or industrial community.

n. Put into place a communication and information dissemination plan, which includes: (1) Marketing your prevention program and services to the target population and local community; (2) Sharing lessons learned and successful program models; and (3) Ensuring Internet and e-mail communication for your organization and key program staff during the first year of funding.

o. You must attend at least one CDC-sponsored meeting of funded agencies. If you sponsor any conferences using CDC funds, you must follow CDC policies for getting approval.

p. Begin gathering information to help develop and implement a plan for obtaining additional resources from non-CDC sources to further support the program implemented through this cooperative agreement and to improve

the chance that it will continue after the end of the project period. We encourage you to contact local organizations and agencies, such as community development agencies, colleges, and universities who may often have information about funding and other types of assistance.

q. Work with other organizations in the community by:

(1) Establishing ongoing collaborations with health departments, community planning groups, academic and local or national research institutions, health care providers, or other local or national resources in designing, implementing, and evaluating interventions; and  
(2) Participating in the HIV prevention community planning process. Participation may include going to meetings; if selected, serving as a member of the group; reviewing and commenting on plans; and becoming familiar with and using information from the community planning process, such as the epidemiology (epi) profile, needs assessment data, and intervention strategies. If selected for funding, an overview of project activities should be presented to your jurisdiction's community planning group.

#### 2. CDC Activities

a. Provide assistance and consultation on program and administrative issues through its partnerships with health departments, national and regional minority organizations, contractors, and other national and local organizations.

b. Meet with you to find out what your training needs are and work with you to ensure those needs are met.

c. Work with the health department to provide training either directly or through its network of HIV/STD prevention training centers. This service is available to persons who supervise, manage, and perform counseling and referral and other outreach activities and for staff who provide direct patient care.

d. Sharing the most up-to-date scientific information on risk factors for HIV infection and prevention measures, and successful program strategies to help prevent HIV infection.

e. Provide assistance and information on rapid test technologies once they become available.

f. Help you establish partnerships with state and local health departments, community planning groups, and other groups who receive federal funding to support HIV/AIDS activities.

g. Make sure that successful prevention interventions, program models, and lessons learned are shared between grantees through meetings,

workshops, conferences, newsletters, Internet, and other avenues of communication.

h. Oversee your success in program and fiscal activities, protection of client privacy, and compliance with other requirements that apply to your organization.

i. During the first year of funding, CDC will work with CBOs and the Health Department to develop standardized evaluation formats and activities for grantees.

#### F. Content

##### *Letter of Intent (LOI)*

A LOI is optional for this program. If you are eligible and you want to apply for funding under this announcement, CDC asks that you let us know your intention to apply by filling out the "Intent to Apply," form found in Attachment 7. Your letter of intent will enable CDC to determine the amount of interest in this program and make sure we have enough of the most qualified reviewers for the application review process.

##### *Applications*

The Program Announcement title and number must appear in the 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.

1. Include page numbers throughout your application. Begin with the first page and number each page through to the last page of the last attachment.

2. Include a Table of Contents which indicates each section and page numbers for the whole package you send in.

3. Begin each separate section of your application on a new page.

4. Do not staple or bind the original document submission or the two copies.

5. Print all materials in a 12 point type size, single-spaced.

6. Use 8½ × 11 paper.

7. Set the margins at a minimum of one inch.

8. Print on one side of the paper only.

##### *Content Guidelines*

The sections that follow give you the questions you have to answer to correctly prepare your application. There are three sections:

- How Do I Write My Proposal Narrative?
- How Much Will My Proposed Program Cost and How Many Staff Do I Need?

- What Other Materials Do I Need to Attach?

When answering the questions below, you must:

1. Label each section, as indicated below, using the section title (e.g., How Do I Write My Proposal Narrative?) and, when appropriate, the name of the subsection (e.g., Justification of Need, Program Activities.)
2. Use the abbreviation N/A (not applicable), if a section does not apply to your application.
3. Include all information that is part of the basic plan (e.g., activity timetables, staff program responsibilities, evaluation plans) in the main section of the application.

**Note:** Your application will be reviewed based on the answers you give to these questions. To be sure you get the best review of your application, use the format provided below when writing your application. Please answer all questions with complete sentences that provide detailed information about your eligibility and proposed activities.

#### How Do I Write My Proposal Narrative?

Your narrative should be no more than 35 pages. The 35 pages does not include your budget and budget narrative. We have included the number of points attached to each section and a suggested number of pages. Sections can vary in length as long as the total number of pages of the narrative is no more than 35. The narrative should address the following areas:

##### 1. Justification of Need

How this section is scored: You will be scored on what information you use and how you use it to demonstrate the need of the target population for your proposed program. Check with the health department for information on the HIV/AIDS statistics and HIV/AIDS needs assessment developed for the community planning process. Use this information when writing your answer for this section.

*Suggested length:* 6 pages.

*Points for this section:* 200 points.

Answer all of the following questions for this section:

(a) How has your proposed target population been affected by the HIV/AIDS epidemic, e.g., how many persons are infected with HIV or diagnosed with AIDS; how many deaths have there been from AIDS; how do socioeconomic factors affect the population? (50 points)

(b) What are the behaviors and other characteristics of your target population that put them at a high risk of becoming infected with HIV or giving HIV to a needle-sharing or sex partner, e.g., unsafe sexual behaviors as indicated by rates of STDs, teen pregnancy rates, or

assessments of risk behaviors; substance use rates; environmental, social, cultural, or language characteristics? (50 points)

(c) What are the barriers to accessing HIV prevention in your target population? How will you address these barriers? (50 points)

(d) Which organizations in your area are providing similar services? Please describe their activities and how your proposed activities will further meet the needs of the target population or improve services provided. (20 points)

(e) Is your proposed target population a priority population as indicated in the comprehensive HIV prevention plan developed through the community planning process? If not, please tell us why your proposed activities are needed? (30 points)

##### 2. Program Activities

How this section is scored: We will look at whether or not your objectives are likely to be achieved; if your activities are sound, doable, creative, specific (how detailed you are in what you want to do), time-phased (have you set a time frame), and measurable (can you show that your activities made a difference).

*Suggested length:* 15 pages.

*Points for this section:* 400 points.

Remember that you will work with the health department and other organizations serving your proposed target population to carry out your program activities. As the applicant, you must describe how all planned services are to be provided either by you or together with another organization.

You will be asked to provide goals and objectives in this section. Goals provide a broad statement of what you intend to accomplish. Objectives should be realistic, specific (who will do what) and measurable.

##### Sample Goal and Objectives

Proposed Intervention (goal): Our program is intended to increase condom use among men who have sex with men who meet in bars.

Reaching clients (objective): Our program will enroll # high-risk persons MSM in our intervention.

Referral and Linkages (objective): Our program will ensure that # HIV-positive persons are successfully referred to a substance abuse program.

Answer all of the following questions for this section:

(a) Proposed Interventions (100 points)

(1) What program model are you planning to use?

(2) Which social-behavioral science theory are you basing your proposed program model on?

(3) What risk behavior(s) or help-seeking behavior(s) will your program model address?

(4) What are the goals for your proposed intervention, i.e., what will happen as a result of your intervention?

(b) Reaching Your Clients (130 points)

(1) What are your objectives and activities planned to reach your proposed target population, during the first year of your proposed project?

(2) What steps will you take to build trust and credibility with this population?

(3) How will you get them to use your services?

(4) How will you use the available social networks to help you provide services?

(5) How will you involve them in planning, evaluating, and modifying your program activities?

(c) Referral and Linkages (80 points)

(1) What are your objectives and activities to help ensure that individuals who are infected with HIV or at a high risk get treatment and other services they need, for example, medical, mental health, drug use treatment, and social services such as housing and transportation?

(2) If you are working with other organizations, which of your proposed activities will be carried out by those organizations, whether they are part of an HIV prevention coalition, subcontractors, or non-paid partners? You must provide in your application a letter of intent from all partnering organizations, as applicable.

(d) Confidentiality (50 points)

(1) What steps will you take to ensure the confidentiality of all records, information, and activities related to your clients?

(2) What steps will you take to ensure the confidentiality of your clients during program activities?

(e) Management and Staffing of the Program (20 points)

(1) How will you manage your program?

(2) What will be the responsibilities and roles of the staff?

(3) What skills and experience does your staff have working with the target population?

(4) What are the responsibilities and roles of those organizations who you want to work with you, e.g., staff responsibilities, skills, experience?

(f) Time line (20 points)

What are the details of your time line? Include information on the most important steps in your project and the approximate dates for when a step is begun and expected to be completed.

### 3. Training, Quality Assurance, and Program Monitoring and Evaluation

How this section is scored: We will look at the quality of: your plan to train your staff; how you will monitor their performance; your plans for seeking technical assistance; how you will measure progress in achieving your objectives; and how you will measure whether you are meeting the needs of your clients.

Applicants must provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant or cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

*Suggested length:* 8 pages.

*Points for this section:* 200 points.

Answer all of the following questions for this section:

(a) What will you do to make sure your staff gets the training they need? Give an estimate of the number of staff to be trained, which staff will be trained, and who will provide the training? (40 points)

(b) How will you routinely monitor your staff's activities to find out if they are following established guidelines and protocols and what training they need? (40 points)

(c) How will you determine and meet your organization's needs in the areas of capacity-building or technical assistance? (20 points)

(d) How will you find out if you are meeting your objectives during the first year of operation? (40 points)

(e) How will you measure whether your services are meeting the needs of the target population and if those you refer for services are using the referral? How will you monitor your activities and those of the organizations working with you as subcontractors or as collaborators? (40 points)

(f) How will you measure the accomplishment for the objectives of this cooperative agreement (stated in section "A. Purpose" of this announcement)? These measures of effectiveness must be objective and quantitative and must measure the intended outcome of the program. (20 points)

### 4. Organizational History and Experience

How this section is scored: We will look at the overall experience of your

organization in working with your proposed target population. This will include how much experience you have related to your proposed project.

*Suggested length:* 8 pages.

*Points for this section:* 250 points.

Answer all of the following questions for this section:

(a) Show evidence of the appropriateness of the proposed staff to the language, age, gender, sexual orientation, disability, literacy, and ethnic/racial/cultural factors of your proposed target population. (50 points)

(b) Provide evidence that your organization reflects the proposed target communities served in the makeup of your board of directors, key staff and management, and that your organization is situated in close geographic proximity to the proposed targeted population, have a history of providing services to the target community and have documented linkages to the targeted populations. (50 points)

(c) What are the specific kinds of health-related services, other than HIV prevention services, that you have provided your target population and for how long? (20 points)

(d) What are the HIV prevention services that you have provided your target population and for how long? (20 points)

(e) How have you ensured that any materials or interventions that you use in your program are culturally sensitive and appropriate for the target population? (30 points)

(f) What other experience does your organization have in providing services to the proposed target population, and for how long? (20 points)

(g) What is your organization's experience in linking with other organizations to provide HIV care or prevention services and ongoing care, as needed, for your clients? (20 points)

(h) What experience does your organization have in record keeping of when and how services are provided, evaluating services, and marketing services to the target population? (25 points)

(i) What experience does your organization have in improving the way services are delivered by finding and accessing other resources (for example, other organizations, materials, proven strategies)? (15 points)

### 5. Communication and Information Dissemination

How this section is scored: We will look at the overall experience of your organization sharing information with other partners, health departments and national organizations.

*Suggested length:* 3 pages.

*Points for this section:* 75 points.

Answer all of the following questions for this section:

(a) How are you planning to market your prevention program and services to the target population and local community? (25 points)

(b) How are you planning to compile lessons learned from the project? (30 points)

(c) How would you ensure access to Internet and e-mail communication for your organization during the first year of funding? (20 points)

*How Much Will My Proposed Program Cost and How Many Staff Do I Need? (Budget)*

In this section, you will need to provide a detailed description of your budget needs and the type and number of staff you will need to put into place to conduct your proposed activities.

Use Form 5161, 424A for the correct format when writing your budget. These forms are available in a PDF format at the following Web site: <http://www.cdc.gov/od/pgo/forminfo.htm>.

You must provide details of your budget for each activity you want to do. You must show how the operating costs will support the activities and objectives you propose.

Your organization must have the capability to access the Internet and to download documents about HIV from CDC and other sites, as well as have electronic mail (e-mail) available for program staff. If you do not have this capability, you must provide a budget for purchasing this equipment.

The following information and questions will help you in writing this part of the application.

(a) What are your budget and staffing needs? This answer should provide the specifics of how you plan to spend funds. For example, how much funding is needed to provide services to the target population, how much is needed to operate your organization (staff, supplies), with whom are you planning to contract, and how much is needed for contracting with other organizations.

CDC may not approve or fund all proposed activities. Give as much detail as possible to support each budget item. List each cost separately when possible.

(b) If you are contracting with other organizations or are applying as a coalition, you must include in the budget the type and name (if known) of the organization(s); how you chose the organization(s); what activities they will do and why they are the best ones to do these activities; a detailed list of the funds you think you will need to pay the organization(s); why and how long you will use their services; and how you

will keep track of what they are doing for you.

(c) Provide a description for each job, including job title, function, general duties, and activities; the rate of pay and whether it is hourly or salary; and the level of effort and how much time will be spent on the activities (give this in a percentage, e.g., 50 percent of time spent on evaluation). Also, if you already know names and titles of persons you will be working with, include this information and a resume, if available. If you don't have names yet, tell us how you plan to recruit these persons. For positions that are voluntary, give a description of the work the volunteers will be doing. Also include the experience and training that is available in relation to the proposed project.

(d) If you ask for indirect costs, you must include a copy of your organization's current agreement concerning your negotiated Federal indirect cost rate.

#### *What Other Materials Do I Need To Attach?*

Following is a list of additional materials to include with your application:

1. A description of funds you receive from any other source to support your HIV/AIDS programs and other similar programs that target the same population included in your proposed plan.

You must include: the name of the organization/source of income, the amount of funding they give you, a very brief description of how you use the funds, and the budget and project time period; and information that tells us that the funds you are requesting through this program announcement will not be used to replace funds received from any other Federal or non-Federal source.

**Note:** CDC-awarded funds can be used to expand or enhance services supported with other Federal or non-Federal funds.

2. Independent audit statements from a certified public accountant for the past 2 years. If you do not have audit statements, provide completed IRS Form 990s for the last 2 years.

3. If you are part of a national organization, please include an original, signed letter from the chief executive officer of the national organization that states that they understand this program announcement and the responsibilities you will have if you are chosen for funding.

4. If you are working with other organizations (e.g., coalition members or referral agencies), you must include a memorandum of understanding or

agreement or a letter to show that the relationship is accepted by both organizations. This memorandum or letter should give details about the activities you propose to do with the organization. This must be submitted each year to show that you are still working with the organization.

#### **G. Submission and Deadline**

##### *Letter of Intent (LOI)*

On or before March 21, 2003, send the completed Intent to Apply Form, found in Attachment 8, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

##### *Application*

Submit the signed original and two copies of Application Form PHS 5161-1 (OMB Number 0920-0428) and your narrative. Forms are available at the following internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

If you do not have access to the internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section at: 770-488-2700. Application forms can be mailed to you.

Your application and narrative must be received by 4 p.m. Eastern Time April 21, 2003. Send your application and narrative to:

Technical Information Management—  
PA# 03003, CDC Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341-4146.

Applications may not be submitted electronically.

#### **CDC Acknowledgement of Application Receipt**

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

**Deadline:** Letters of intent and applications will be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or national disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

#### **H. Evaluation Criteria**

Your application will not be compared to other applications. It will only be reviewed based on the information contained in section the "Content" section of this announcement. This will be done by an independent review group that is chosen by CDC.

With the recommendations from the independent review group, CDC will conduct pre-decisional site visits to those applications that score high enough to be considered for funding. This will be the second tier of the selection process. The Pre-decisional site visits will account for a total of 1,000 points. The following areas will be evaluated during this process:

##### *1. Recipient Capability Assessment (300 points)*

CDC's Procurement and Grants Office (PGO) will conduct a recipient capability assessment (RCA) to evaluate the capacity of the agency to manage the funds that will be provided by CDC. This will be conducted by either PGO staff or another selected agent.

##### *2. Proposed Program (250 Points)*

- The purpose of this section is to assess the feasibility of the proposed program and the capability of the organization to effectively implement HIV prevention interventions.

- Proposed intervention(s) based on scientific theory or an evidence-based logic model.

- Specific, measurable, achievable, realistic and time phased goals and objectives (SMART).

- Target population reflect the priorities identified in the HIV Prevention Comprehensive Plan or are based on epidemiological data or needs assessment.

- Interventions reflect the priorities identified in the HIV Prevention Comprehensive Plan.

- Evaluation plan for proposed program.

##### *3. Programmatic Infrastructure (200 points)*

The purpose of this section is to assess the extent and relevance of organization's experience, capacity, and ability to identify and address the needs of the proposed target population and to effectively and efficiently implement the proposed activities, including:

- Organizational structure and planned collaborations.
- Past and current experience in developing and implementing effective and efficient HIV prevention strategies and activities.
- Experience and ability in collaborating with governmental and non-governmental organizations, including other national agencies or organizations, State and local health departments, community planning groups, and State and local non-governmental organizations that provide HIV prevention services.
- Capacity to obtain meaningful input and representation from members of the target population(s).
- Capacity to provide culturally competent and appropriate services which respond effectively to the cultural, gender, sexual orientation, race/ethnicity, age groups, environmental, social, and linguistic characteristics of the target population(s) (when appropriate).
- Capacity to identify and provide training to program staff.
- Ability to track data on services provided and use it to plan future interventions and to improve available services.

#### 4. Organizational Infrastructure (150 points)

The purpose of this section is to assess the capacity of the organization to effectively and efficiently sustain the proposed program.

- Organizational By Laws, Mission and Vision.
- Composition, role, experience and involvement of the board of directors in administering the agency.
- Current fiscal systems to track available funding.
- Personnel process and procedures.
- Organizational protocols and procedures (*i.e.* security, confidentiality, grievances, etc)
- Organizational Capacity for fund raising

#### 5. Health Department Review (100 points)

The purpose of this section is to obtain input for the department of health regarding the proposed program plan.

- Review the program plan (*i.e.*, proposed target population, intervention, number of persons to be served, and service location) to assess consistency of the proposed target population and intervention(s) with the HIV Prevention Comprehensive Plan;
- Rate the past performance with state/city funded programs.
- Provide a letter of support or non-support for funding to CDC.

The points from all five sections will be added and a final score will be assigned. In order to be considered for funding you must score at least 700 points during the pre-decisional site visits. Failure to do so will disable your agency from receiving funds from CDC.

### I. Other Requirements

#### Technical Reporting Requirements

If you are selected for funding, you must let CDC know how you are doing by sending to us an original plus two (2) copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application and must include the following elements:
  - a. Current Budget Period Activities Objectives.
  - b. Current Budget Period Financial Progress.
  - c. New Budget Period Program Proposed Activity Objectives.
  - d. Detailed Line-Item Budget and Justification.
  - e. Additional Requested Information.
2. Financial status report, no later than 90 days after the end of each budget period.
3. Final financial and performance reports, no later than 90 days after the end of the project period.
4. Quarterly reports on the numbers of HIV antibody counseling, testing, and referral activities you have done.

Send all reports to the Grants Management Specialist identified in the "Where To Obtain Additional Information" section of this announcement.

The following are additional requirements that must be met if awarded a cooperative agreement under this announcement. For a complete description of each, see Attachment 1 of the program announcement as posted on the CDC Web site.

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-5 HIV Program Review Panel Requirements
- 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
- AR-14 Accounting System Requirements

### J. Where To Obtain Additional Information

CDC suggests that you do not use the program announcement in the **Federal Register**. Instead, use the version posted on the CDC Web site to write your application. This copy includes the forms you need and has additional information to help you through the process. The internet address is: <http://www.cdc.gov>.

Click on "Funding" the "Grants and Cooperative Agreements."

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For business management and budget assistance, contact: Vincent Falzone, Grants Management Specialist, Procurement and Grants Office, Centers for disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: (770) 488-2763, email address: [vfalzone@cdc.gov](mailto:vfalzone@cdc.gov).

For Program technical assistance, contact: Angel Ortiz, J.D., Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention, Prevention Program Branch, 1600 Clifton Road, MS E-58, Atlanta, GA 30333, Telephone (404) 639-5197, E-mail: [air4@cdc.gov](mailto:air4@cdc.gov).

See also the DHAP home page on the Internet: [www.cdc.gov/hiv](http://www.cdc.gov/hiv). To receive additional written information, call The National Prevention Information Network (NPIN) at 1-800-458-5231 (TTY users: 1-800-243-7012) or visit their Web site: <http://www.cdcpin.org/program> or

You can send requests by fax to: 1-888-282-7681 or e-mail to: [application-cbo@cdcpin.org](mailto:application-cbo@cdcpin.org).

This information, including 5161 forms in PDF and word processing formats, is also posted on the Division of HIV/AIDS Prevention (DHAP) Web site at: <http://www.cdc.gov/hiv> or by contacting NPIN either through their toll-free number: 1-800-458-5231 or their Web site: <http://www.cdcpin.org/program>.

CDC also maintains a Listserv (HIV-PREV) related to this program announcement. If you decide to subscribe to the HIV-PREV Listserv, you will be able to send questions and will receive an answer and information through e-mail. This would include the latest news regarding the program announcement. Frequently asked questions on the Listserv will be posted to the DHAP Website. You can subscribe

to the Listserv on-line or via e-mail by sending a message to:  
*listserv@listserv.cdc.gov* and writing the following in the body of the message: subscribe HIV-prev first name last name (e.g., subscribe HIV-prev john smith).

Dated: February 10, 2003.

**Sandra R. Manning,**

*Director, Procurement and Grants Office,  
Centers for Disease Control and Prevention.*

[FR Doc. 03-3922 Filed 2-18-03; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03027]

#### Grants for New Investigator Training Awards for Unintentional Injury, Violence Related Injury, Acute Care, Disability, and Rehabilitation-Related Research; Notice of Availability of Funds Amendment

A notice announcing the availability of fiscal year (FY) 2003 funds for grants for new investigator training awards in four research areas: unintentional injury prevention, violence-related injury prevention, injury-related acute care and disability research, and injury-related biomechanics research published in the **Federal Register** on February 7, 2003, Volume 68, Number 26, and pages 6483-6488. The notice is amended as follows: On page 6483, second column, the Program Announcement 03027 title should read: Grants for New Investigator Training awards for Unintentional Injury, Violence related Injury, Biomechanics, Acute Care, Disability, and Rehabilitation-Related Research.

Dated: February 7, 2003.

**Sandra R. Manning,**

*CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 03-3921 Filed 2-18-03; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01E-0403]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; VALCYTE

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for VALCYTE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3460.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product VALCYTE (valganciclovir hydrochloride). VALCYTE is indicated for treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VALCYTE (U.S. Patent No. 6,083,953) from Syntex, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 31, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VALCYTE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VALCYTE is 2,101 days. Of this time, 1,919 days occurred during the testing phase of the regulatory review period, while 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* June 30, 1995. The applicant claims July 26, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 30, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 29, 2000. The applicant claims September 28, 2000, as the date the new drug application (NDA) for VALCYTE (NDA 21-304) was initially submitted. However, FDA records indicate that NDA 21-304 was submitted on September 29, 2000.

3. *The date the application was approved:* March 29, 2001. FDA has verified the applicant's claim that NDA 21-304 was approved on March 29, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension,