

(4) Reserve Banks will allocate recirculation *de minimis* exemptions to depository institutions for each zone or sub-zone where they do business. Reserve Banks will apply the exemptions to depository institutions' total cross-shipped volume.<sup>33</sup> *De minimis* exemptions may not be transferred from one zone or sub-zone to another. Unused *de minimis* exemptions will expire at the end of each quarter. Initially, the *de minimis* exemption will be 875 bundles per quarter. Reserve Banks will review the level of the *de minimis* exemption annually.

(5) Reserve Banks will monitor depository institutions' order and deposit activity weekly for cross-shipping. For the purposes of monitoring cross-shipping activity, a week includes consecutive days from Monday through Friday. If, in the judgment of Reserve Banks, a depository institution circumvents the recirculation policy by reducing its cross-shipping volume without increasing recirculation, such as would be the case if it alternated the weeks in which it orders and deposits currency, Reserve Banks will apply the recirculation fee to fit notes in such deposits.

(6) Reserve Banks will determine the number of fit notes processed from each institution's deposits as a percentage of total notes deposited by that institution during each month. Reserve Banks will then apply this monthly average fitness rate by zone or sub-zone to an institution's weekly deposits during that month to determine how much currency it cross-shipped.<sup>34</sup>

(7) Reserve Banks publish currency fitness and equipment guidelines at [http://www.frbservices.org/Cash/pdf/FRB\\_Fitness\\_Standards.pdf](http://www.frbservices.org/Cash/pdf/FRB_Fitness_Standards.pdf).

#### Phased Implementation

The Reserve Banks will implement the recirculation policy in two phases. The first phase will expand the custodial inventory program to all eligible participants. One year later, in the second phase, the Reserve Banks will begin assessing the recirculation fee, provided however, that they have implemented a currency quality policy.

By order of the Board of Governors of the Federal Reserve System, March 17, 2006.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Request for Applications for the National Centers of Excellence in Women's Health (CoE) and the National Community Centers of Excellence in Women's Health (CCOE)—Ambassadors for Change Program

**AGENCY:** Office of the Secretary, Office of Public Health and Science.

**ACTION:** Notice.

*Funding Opportunity Title:* Request for Applications for the National Centers of Excellence in Women's Health (CoE) and the National Community Centers of Excellence in Women's Health (CCOE)—Ambassadors for Change Program.

*Announcement Type:* Competitive Cooperative Agreement—FY 2006—Initial Announcement.

*Funding Opportunity Number:* Not applicable.

*Catalog of Federal Domestic Assistance:* The Catalog of Federal Domestic Assistance number is 93.013.

**DATES:** To receive consideration applications must be received by the Office of Grants Management, Office of Public Health and Science (OPHS), Department of Health and Human Services (DHHS), no later than 5 p.m. Eastern Time on May 22, 2006.

**Authority:** This program is authorized by 42 U.S.C. 300u-2(a).

**SUMMARY:** The National Centers of Excellence in Women's Health and the National Community Centers of Excellence in Women's Health programs provide funding to academic health centers and community-based organizations to enhance their women's health programs through the integration of these components: (1) Leadership development for women, (2) training for lay, allied health, and professional health care providers, (3) public education and outreach with special emphasis on outreach to minority women, (4) comprehensive health service delivery that includes gender and age-appropriate preventive services and allied health professionals as members of the comprehensive care team, and (5) basic science, clinical and community-based research. In addition,

the community centers must replicate their National Community Center of Excellence in Women's Health (CCOE) model in another organization or community.

#### I. Funding Opportunity Description

The goals of the Ambassador for Change program are to:

1. Increase the number of health professionals, including allied health professionals, trained to work with underserved and diverse women and to increase their leadership and advocacy skills.
2. Increase the number of women, including American Indian or Alaska Native, Black or African American, Hispanic or Latino, Asian, or Native Hawaiian or Other Pacific Islander, who pursue health careers and increase the leadership skills and opportunities for women in the community and for women faculty in academic settings.
3. Eliminate health disparities for women who are underserved due to age, gender, race/ethnicity, education, income, or disabilities.
4. Reduce the fragmentation of women's health services and access barriers by using a framework that coordinates and integrates comprehensive health services. Comprehensive health services include gender and age-appropriate preventive services and allied health professionals on the service delivery team.
5. Increase the women's health knowledge base by conducting gender-based research and/or by involving the community in identifying and conducting research related to and responsive to the health needs and issues of concern to underserved and minority women in the target community.
6. Empower women, especially underserved and minority women, as health care consumers and decision-makers.

The Ambassadors for Change must continue to: (1) Develop and/or strengthen a framework to bring together a comprehensive array of services for women; (2) train a cadre of diverse health care providers that include allied health professionals and community health workers; (3) promote leadership/career development for diverse women in the health professions, including allied health professions and community health workers, and women/girls in the community; (4) enhance public education and outreach activities in women's health with an emphasis on gender-specific and age-appropriate prevention and/or reduction of illness or injuries that appear controllable through increased

<sup>33</sup> Exemptions will not be denomination-specific.

<sup>34</sup> For example, if the notes processed from an institution's deposits in a zone or sub-zone included 80 percent fit currency in January, the Reserve Bank would multiply that institution's weekly deposits during January by 80 percent to determine how much fit currency the institution deposited each week of the month. The Reserve Bank will then compare that institution's weekly deposits of fit currency with their weekly orders in the zone or sub-zone to determine the amount of currency the institution cross-shipped. At the end of the quarter, the Reserve Bank will assess fees for each bundle of currency cross-shipped above the *de minimis* exemption.

knowledge that leads to a modification of behavior; (5) participate in any national evaluation of the CoE and/or CCOE program; (6) conduct basic, clinical and/or community-based research in women's health; and (7) provide advice and guidance to other organizations interested in learning more about the OWH CoE and CCOE programs.

At a minimum, each Ambassador for Change awardee must maintain a physically-identifiable clinical care center for the delivery of comprehensive, interdisciplinary health care that includes gender and age-appropriate preventive services for women. The clinical care center must have permanent signage that identifies it as a National Center of Excellence in Women's Health or a National Community Center of Excellence in Women's Health supported by the U.S. Department of Health and Human Services. The clinical care center must be devoted to women-friendly, women-centered, women-relevant care delivered from a multidisciplinary, holistic, and culturally and linguistically appropriate perspective. The clinical care center must also have a women's health clinical intake form, referral and tracking system, and procedures for identifying and counting the women served by the program and for tracking the cost of services provided to women who receive interdisciplinary care through the program. Sites must be able to differentiate the services provided to women counted as CoE or CCOE patients compared to other patients.

## II. Award Information

The CoE/CCOE—Ambassadors for Change program will be supported through the cooperative agreement mechanism. The OWH anticipates making up to 12 new 1-year awards in FY 2006. The anticipated start date for new awards is September 1, 2006, and the anticipated period of performance is September 1, 2006, through August 31, 2007. Approximately \$400,000 is available to make awards between \$25,000–\$50,000 total cost (direct and indirect) for a 12-month budget period. The total amount that may be requested by academic health centers is \$25,000 and the total amount that may be requested by community-based organizations is \$50,000.

CoE/CCOE—Ambassadors for Change programs will continue to be recognized by the OWH as National Centers of Excellence in Women's Health and National Community Centers of Excellence in Women's Health with all the privileges granted these programs by

the OWH. As such, the Ambassadors for Change will continue to attend the CoE/CCOE Center Directors' meetings, have the opportunity to participate in joint projects initiated and funded by the OWH, remain on the list serve to continue to have access to information and funding opportunities, be a full-participating member of the CoE/CCOE Research Coordinating Center (if applicable), be site visited as needed, be listed on the OWH Web site with links to their CoE/CCOE Web site, and have their products/activities listed on the virtual resource center.

The eight CoEs whose options years were renewed through September 2006 are eligible to apply for this award.

The OWH will provide the technical assistance and oversight necessary for the implementation, conduct, and assessment of the Ambassador for Change program activities.

### *The applicant shall:*

1. Implement the program described in the application.
2. Participate in and pay for attendance at the two annual meetings of the CoE and CCOE Center Directors and the joint CoE/CCOE Center Directors' meetings.
3. Participate in any national evaluations of the CoE and CCOE programs following the guidance provided by the OWH contractor.
4. Maintain the CoE or CCOE Web site.
5. Display permanent signage designating the facility as a National Center of Excellence in Women's Health or National Community Center of Excellence in Women's Health.
6. Participate in special meetings (*i.e.*, CoE/CCOE Working Group meetings) and projects/funding opportunities identified and/or offered by the OWH.

7. Adhere to all program requirements specified in the Notice of Grant Award.

8. Submit required annual progress and financial reports by the due dates stated in this announcement and the Notice of Grant Award.

9. Participate in the projects of the Research Coordinating Center (if applicable).

### *The Federal Government will:*

1. Participate in at least two annual meetings with the CoE/CCOE Center Directors and/or Program Coordinators.

2. Participate in a national evaluation of the CoE or CCOE programs using guidance provided by the OWH contractor.

3. Review and decide on requested project modifications.

4. Site visit CoE/CCOE facilities, as needed.

5. Review all reports submitted by the grantees.

6. Facilitate review and clearance of all Center publications to insure adherence to DHHS policies.

The DHHS is committed to achieving the health promotion and disease prevention Objectives of Healthy People 2010 and the Healthy U.S. Initiative. Emphasis will be placed on aligning the CoE/CCOE—Ambassadors for Change activities and programs with the DHHS Secretary's four priority areas—heart disease, cancer, diabetes, and HIV/AIDS with an increased emphasis on adolescents, elderly women, mental health, and violence against women—and with the Healthy People 2010: Goal 2—eliminating health disparities due to age, gender, race/ethnicity, education, income, disability, or living in rural localities. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 Web site: <http://www.health.gov/healthypeople>. Another reference is the *Healthy People 2000 Review—1998–99*. One free copy may be obtained from the National Center for Health Statistics (NCHS), 6525 Belcrest Road, Room 1064, Hyattsville, MD 20782 or telephone (301) 458–4636 [DHHS Publication No. (PHS) 99–1256]. This document may also be downloaded from the NCHS Web site: <http://www.cdc.gov/nchs>. Also, *Steps to a HealthierUS*, a program of the Department to help implement the Healthy U.S. initiative, advances the goal of helping Americans live longer, better, and healthier lives. It lays out DHHS priorities and programs for *Steps to a HealthierUS*, focusing attention on the importance of prevention and promising approaches for promoting healthy environments.

## III. Eligibility Information

1. *Eligible Applicants.* Eligible applicants are OWH funded National Centers of Excellence in Women's Health (CoE) whose funding ends in September 2006 without remaining option years and National Community Centers of Excellence in Women's Health (CCOE) programs whose funding ends in September 2006. The purpose of this award is to continue, at a reduced level of effort, those CoEs or CCOEs that were funded by the DHHS Office on Women's Health (OWH). The program is monitored by OWH program staff to ensure the establishment of a comprehensive, integrated, holistic system of care for women across the life span. In addition the program shall be evaluated by the OWH. As such, this competition is limited to the organizations specified above since they are the only ones that meet the eligibility criteria.

2. *Cost Sharing or Matching Funds.* Cost sharing, matching funds, and cost participation is not a requirement of this grant.

#### IV. Application and Submission Information

1. *Address to Request Application Package:* Application kits may be requested by calling (240) 453-8822 or writing to the Office of Grants Management, Office of Public Health and Science, Department of Health and Human Services, 1101 Wooten Parkway, Suite 550, Rockville, MD 20852. Applicants may fax a written request to the OPHS Office of Grants Management to obtain a hard copy of the applications kit at (240) 453-8823. Applications must be prepared using Form OPHS-1.

2. *Content and Form of Application and Submission:* At a minimum, each application for a cooperative agreement grant funded under this announcement must:

Present a plan to continue integrating all components of the program. The CCOEs are not required to continue the replication component but preference will be given to programs that plan to continue to provide technical assistance to their replication site. Additionally, CCOEs that actively participate in the Research Coordinating Center (RCC) projects will be considered as fulfilling the requirements for the research component. A statement of willingness to participate in the RCC activities must be included in the application, if applicable. Discuss a plan to continue the involvement of the CoE or CCOE advisory board and their role as it relates to the Ambassadors for Change program.

Be a sustainable organization capable of providing coordinated and integrated women's health services in the targeted community. The applicant will need to define the components of comprehensive, multi-disciplinary care, demonstrate that they are culturally, linguistically, and gender and age appropriate, and show that they have a clear and sustainable framework for providing those services.

Describe how support, advice, and guidance will be provided to CoEs, CCOEs, and the Demonstration CoEs, through a variety of opportunities, such as the ELAM program, promotoras trainings, discussions at Center Directors' meetings, etc. These activities may be supported by outside funding or sponsors in keeping with the government partnership ethics guidance.

The applicant must indicate their willingness to participate in a national

evaluation of the program to be conducted under the leadership of the OWH contractor.

The Project Narrative must not exceed a total of 20 *double-spaced* pages, excluding the appendices. All pages must be numbered clearly and sequentially. The application must be typed *double-spaced* on one side of plain 8½" x 11" white paper, using at least a 12 point font, and contain 1" margins all around. The application should be organized in accordance with the format presented in the Program Guidelines. An outline for the minimum information to be included in the "Project Narrative" section is presented below.

Applications submitted via hard copy must be stapled and/or otherwise securely bound. Applicants are required to submit an original ink-signed and dated application and two photocopies. All applicants must pay particular attention to structuring the narrative to respond clearly and fully to each review Factor and associated review criteria.

#### I. Background

- A. Overview of CoE/CCOE program.
- B. Goal and purpose of the CoE or CCOE AFC program, including population to be served.
- C. Primary area(s) of expertise to serve as a Technical Consultant (provide a list the AFC services at the beginning of this section).

#### II. Implementation Plan

- A. Describe the level of effort to be maintained for each AFC CoE or CCOE program component.
- B. Describe how the components will continue to be integrated.
- C. The applicant must discuss/describe the resources available to support each component, plans for maintaining components. In addition, describe the relationship of each integrated component to the overall goals and objectives of the CoE/CCOE Ambassador for Change program.
- D. Describe how support, advice, and guidance will be provided to the CoEs, CCOEs, and Demonstration CoEs.
- E. Describe plans to develop and maintain partnerships and include in the appendix signed partnership agreements that specify the services the partner will provide and the contact information for the person serving as the main liaison for the partnering organization.
- F. State willingness to participate in any CoE or CCOE national evaluation.

#### III. Management Plan

- A. Key project staff and their resumes for budgeted staff affiliated with the new CoE/CCOE Ambassador for Change program
- B. Staff responsibilities
- C. CoE or CCOE Advisory Board

#### Appendices

- A. Required Forms (Assurance of Compliance Form, etc.)
- B. Key Staff Resumes

- C. AFC Program Staff Chart
- D. Institutional Letters of Support
- E. Signed partnership agreements
- F. Other attachments

3. *Submission Dates and Times.* To be considered for review, applications must be received by the Office of Grants Management, Office of Public Health and Science, by 5:00 p.m. Eastern Time on May 22, 2006. Applications will be considered as meeting the deadline if they are received on or before the deadline date. The application due date requirement in this announcement supercedes the instructions in the OPHS-1.

#### Submission Mechanisms

The Office of Public Health and Science (OPHS) provides multiple mechanisms for the submission of applications, as described in the following sections. Applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of applications submitted using any of these mechanisms. Applications submitted to the OPHS Office of Grants Management after the deadlines described below will not be accepted for review. Applications which do not conform to the requirements of the grant announcement will not be accepted for review and will be returned to the applicant.

Applications may only be submitted electronically via the electronic submission mechanisms specified below. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, will not be accepted for review. While applications are accepted in hard copy, the use of the electronic application submission capabilities provided by the OPHS eGrants system or the Grants.gov Web site Portal is encouraged.

Electronic grant application submissions must be submitted no later than 5 p.m. Eastern Time on the deadline date specified in the SUBMISSION DATES AND TIMES section of the announcement using one of the electronic submission mechanisms specified below. All required hard copy original signatures and mail-in items must be received by the OPHS Office of Grants Management no later than 5 p.m. Eastern Time on the next business day after the deadline date specified in the SUBMISSION DATES AND TIMES section of the announcement.

Applications will not be considered valid until all electronic application components, hard copy original signatures, and mail-in items are received by the OPHS Office of Grants

Management according to the deadlines specified above. Application submissions that do not adhere to the due date requirements will be considered late and will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process, and to submit early on the due date or before. This will aid in addressing any problems with submissions prior to the application deadline.

#### *Electronic Submissions Via the Grants.gov Web Site Portal*

The Grants.gov Web site Portal provides organizations with the ability to submit applications for OPHS grant opportunities. Organizations must successfully complete the necessary registration processes in order to submit an application. Information about this system is available on the Grants.gov Web site, <http://www.grants.gov>.

In addition to electronically submitted materials, applicants may be required to submit hard copy signatures for certain Program related forms, or original materials as required by the announcement. It is imperative that the applicant review both the grant announcement, as well as the application guidance provided within the Grants.gov application package, to determine such requirements. Any required hard copy materials, or documents that require a signature, must be submitted separately via mail to the OPHS Office of Grants Management, and, if required, must contain the original signature of an individual authorized to act for the applicant agency and the obligations imposed by the terms and conditions of the grant award.

Electronic applications submitted via the Grants.gov Web site Portal must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. All required mail-in items must be received by the due date requirements specified above. Mail-in items may only include publications, resumes, or organizational documentation.

Upon completion of a successful electronic application submission via the Grants.gov Web site Portal, the applicant will be provided with a confirmation page from Grants.gov indicating the date and time (Eastern Time) of the electronic application submission, as well as the Grants.gov Receipt Number. It is critical that the applicant print and retain this confirmation for their records, as well as a copy of the entire application package.

All applications submitted via the Grants.gov Web site Portal will be validated by Grants.gov. Any applications deemed "Invalid" by the Grants.gov Web site Portal will not be transferred to the OPHS eGrants system, and OPHS has no responsibility for any application that is not validated and transferred to OPHS from the Grants.gov Web site Portal. Grants.gov will notify the applicant regarding the application validation status. Once the application is successfully validated by the Grants.gov Web site Portal, applicants should immediately mail all required hard copy materials to the OPHS Office of Grants Management to be received by the deadlines specified above. It is critical that the applicant clearly identify the Organization name and Grants.gov Application Receipt Number on all hard copy materials.

Once the application is validated by Grants.gov, it will be electronically transferred to the OPHS eGrants system for processing. Upon receipt of both the electronic application from the Grants.gov Web site Portal, and the required hard copy mail-in items, applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of the application submitted using the Grants.gov Web site Portal. Applicants should contact Grants.gov regarding any questions or concerns regarding the electronic application process conducted through the Grants.gov Web site Portal.

#### *Electronic Submissions Via the OPHS eGrants System*

The OPHS electronic grants management system, eGrants, provides for applications to be submitted electronically. Information about this system is available on the OPHS eGrants Web site, <https://egrants.osophs.dhhs.gov>, or may be requested from the OPHS Office of Grants Management at (240) 453-8822.

When submitting applications via the OPHS eGrants system, applicants are required to submit a hard copy of the application face page (Standard Form 424) with the original signature of an individual authorized to act for the applicant agency and assume the obligations imposed by the terms and conditions of the grant award. If required, applicants will also need to submit a hard copy of the Standard Form LLL and/or certain Program related forms (e.g., Program Certifications) with the original signature of an individual authorized to act for the applicant agency.

Electronic applications submitted via the OPHS eGrants system must contain

all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. The applicant may identify specific mail-in items to be sent to the Office of Grants Management separate from the electronic submission; however these mail-in items must be entered on the eGrants Application Checklist at the time of electronic submission, and must be received by the due date requirements specified above. Mail-in items may only include publications, resumes, or organizational documentation.

Upon completion of a successful electronic application submission, the OPHS eGrants system will provide the applicant with a confirmation page indicating the date and time (Eastern Time) of the electronic application submission. This confirmation page will also provide a listing of all items that constitute the final application submission including all electronic application components, required hard copy original signatures, and mail-in items, as well as the mailing address of the OPHS Office of Grants Management where all required hard copy materials must be submitted.

As items are received by the OPHS Office of Grants Management, the electronic application status will be updated to reflect the receipt of mail-in items. It is recommended that the applicant monitor the status of their application in the OPHS eGrants system to ensure that all signatures and mail-in items are received.

#### *Mailed or Hand-Delivered Hard Copy Applications*

Applicants who submit applications in hard copy (via mail or hand-delivered) are required to submit an original and two copies of the application. The original application must be signed by an individual authorized to act for the applicant agency or organization and to assume for the organization the obligations imposed by the terms and conditions of the grant award.

Mailed or hand-delivered applications will be considered as meeting the deadline if they are received by the OPHS Office of Grant Management on or before 5 p.m. Eastern Time on the deadline date specified in the SUBMISSION DATES AND TIME section of the announcement. The application deadline date requirement specified in this announcement supersedes the instructions in the OPHS-1. Applications that do not meet the deadline will be returned to the applicant unread.

Applications will be screened upon receipt. Those that are judged to be incomplete or arrive after the deadline will not be reviewed. Applications that exceed the specified amount for a twelve-month budget period may also not be reviewed. Applications that are judged to be in compliance will be reviewed for technical merit in accordance with DHHS policies. Applications will be evaluated by a technical review panel composed of experts in the fields of program management, service delivery, outreach, health education, research, leadership development and evaluation. Consideration for award will be given to applicants that best demonstrate progress and/or plausible strategies for eliminating health disparities through the integration of training, leadership/career development, public education and outreach, comprehensive services that include gender and age-appropriate preventive services, and research. Applicants are advised to pay close attention to the specific program guidelines and general instructions in the application kit.

4. *Intergovernmental Review*: This program is subject to the Public Health Systems Reporting Requirements. Under these requirements, a community-based non-governmental applicant must prepare and submit a Public Health System Impact Statement (PHIS). Applicants shall submit a copy of the application face page (SF-424) and a one page summary of the project, called the Public Health System Impact Statement. The PHIS 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, non-governmental organizations within their jurisdictions.

Community-based, non-governmental 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), (b) a summary of the project (PHIS), 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 PHIS to these authorities must be contained in the application materials submitted to the OWH.

This program is also subject to the requirements of Executive Order 12372

that 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 that 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 SPOC 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 in each affected State. A complete list of SPOC may be found at the following Web site: <http://www.whitehouse.gov/omb/grants/spoc.html> The due date for State process recommendations is 60 days after the application deadline. The OWH 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.)

5. *Funding Restrictions*: A majority of the funds must be used to support staff (direct labor) and efforts aimed at coordinating and integrating the components of the program and travel to the two Center Directors' Meetings held each year. The senior person responsible for the program shall continue to devote the maximum effort needed to maintain program excellence. Funds may also be used for program related travel.

Funds may *not* be used for construction, building alterations, equipment, printing, food, and medical treatment. All budget requests must be justified fully in terms of the proposed goals and objectives and include an itemized computational explanation/breakout of how costs were determined.

The CoE and CCOE Center Directors meet twice a year. A portion of these meetings will be devoted to the Ambassadors for Change program. The budget should include a request for funds to pay for the travel, lodging, and meals for the two Center Directors' meetings. The first meeting is usually held between mid-November and mid-December and the second Center Directors' meeting is usually held in May. This year the joint Center Directors' meetings will be held December 4, 2006. CCOE Center Directors are encouraged to bring the person with primary responsibility for the day-to-day management of the

Ambassador for Change program to these meetings and should include their travel cost in the budget.

6. *Other Submission Requirements*: Beginning October 1, 2003, all applicants are required to obtain a Data Universal Numbering System (DUNS) number as preparation for doing business electronically with the Federal Government. The DUNS number must be obtained prior to applying for OWH funds. The DUNS number is a nine-character identification code provided by the commercial company Dun & Bradstreet, and serves as a unique identifier of business entities. There is no charge for requesting a DUNS number, and you may register and obtain a DUNS number by either of the following methods:

Telephone: 1-866-705-5711.

Web site: <http://www.dnb.com/product/eupdate/requestOptions.html>. Be sure to click on the link that reads, "DUNS Number Only" at the right hand, bottom corner of the screen to access the free registration page. Please note that registration via the Web site may take up to 30 business days to complete.

## V. Application Review Information

1. *Criteria*: The technical review of applications will consider the following factors:

*Factor 1: Level of Integration of the Components and Gender-Based Medicine at the Institution (30%)*

The CoE/CCOE Ambassadors for Change Program model shall include: (a) Training for professional, allied health, and lay health care workers serving underserved diverse women, (b) leadership/career development for women providers and underserved women/girls in the community, including American Indian or Alaska Native, Black or African American, Hispanic or Latino, Asian, and Native Hawaiian or Other Pacific Islander women/girls, (c) outreach and public education, (d) comprehensive multidisciplinary women's health services that include gender and age-appropriate preventive services, (e) gender-based research originating at the institution and/or involved with the CoE/CCOE Research Coordinating Center. All components shall be in place/operational and integrated with one another at the time the application is submitted. The applicant must discuss/describe the resources available to support each component, plans for maintaining components, and the relationship of each integrated component to the overall goals and objectives of the CoE/CCOE Ambassador

for Change program. In addition the applicant must state a willingness to participate in any CoE or CCOE national evaluation.

*Factor 2: Degree of Self-Sustainment at the Parent Institution (30%)*

Applicant organization's capability to manage the project as determined by the qualifications of the proposed staff; proposed staff level of effort; management experience of the staff; and the experience, resources and role of each partner organization as it relates to the needs and programs/activities of the CoE/CCOE Ambassador for Change program; integration of allied health professionals into the CoE/CCOE AFC program; and integration of the CoE/CCOE AFC advisory board into the program's activities. Detailed position descriptions, resumes of key staff, an AFC staffing chart, and letter of support from key institutional administrator that demonstrate a commitment to the AFC program (form letters are discouraged) should be included in the appendix. The AFC Program Staff chart shall include the name, degrees earned, position, FTE equivalent, race/ethnicity and gender of each person/partner working on the AFC program. This chart shall provide information to identify the number of people involved in the program and to identify trends in demographics. The management plan should also describe succession planning for key personnel and cross training of responsibilities. Thoughtful succession planning and cross training of responsibilities should contribute to the sustainability of the program and provide promotion potential.

*Factor 3: Agreement To Serve as a Technical Consultant to Other Sites on Your Most Successful Component (30%)*

A clear statement of willingness to provide technical consultation to other academic health centers interest in the CoE model or other community-based organizations interested in the CCOE model could include work with the Executive Leadership in Academic Medicine Program, a promotoras training program, presentations at CoE and CCOE Center Directors' meetings, technical assistance visits to other CoE/CCOE sites, etc.

*Factor 4: Partnerships (10%)*

The CoE or CCOE shall maintain existing partnership and develop new ones within their region and neighboring regions and with government-sponsored agencies and organizations:

The Regional Women's Health Coordinator (RWHC) in their region.

The RWHCs and contact information can be found at <http://www.4woman.gov/owh/reg/>.

The Minority Women's Health Panel of Experts (if there is one in their region). The MWHPEs and contact information can be found at <http://www.4woman.gov/owh/minority.htm#mwhpe>.

DHHS agencies (HRSA, OMH/OPHS, IHS, NIH, CDC, FDA, etc.).

Other government and non-government agencies.

The partnerships shall work towards: Improving diversity at their institution regarding populations served, culturally competent materials and center staff, and

Continuing to transform the programs through leadership, outreach especially to adolescents and elderly women, prevention programs on heart disease, diabetes/obesity, cancer, HIV/AIDS, mental health, and violence against women, and underserved women, including the American Indian population.

Partnership agreements shall be included in the appendix of the application.

*2. Review and Selection Process:*

Accepted applications will be reviewed for technical merit in accordance with DHHS policies. Applications will be evaluated by a objective/technical review panel composed of experts in the fields of program management, academic/community service delivery, outreach, health education, research, and leadership development and evaluation. Consideration for award will be given to applicants that meet the goals and review criteria of the CoE/CCOE Ambassadors for Change programs.

Funding decisions will be made by the OWH, and will take into consideration the recommendations and ratings of the review panel, program needs, stated preferences, and the organization's women's health experience.

**VI. Award Administration Information**

*1. Award Notices:* Within a month of the review of all applications, applicants not scoring in the funding range will receive a letter stating that they have not been recommended for funding. Applicants selected for funding support will receive a Notice of Grant Award signed by the grants officer. This is the authorizing document to begin performing grant activities and it will be sent electronically and followed up with a mailed copy. Pre-award costs are not supported by the OWH.

*2. Administrative and National Policy Requirements:* (1) In accepting this

award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of the 45 CFR parts 74 and 92, currently in effect or implemented during the period of this grant. (2) Requests that require prior approval from the awarding office (See Chapter 8, PHS Grants Policy Statement) must be submitted in writing to the OPHS Grants Management Office. Only responses signed by the Grants Management Officer are to be considered valid. Grantees who take action on the basis of responses from other officials do so at their own risk. Such responses will not be considered binding by or upon the OWH. (3) Responses to reporting requirements, conditions, and requests for post-award amendments must be mailed to the Office of Grants Management at the address indicated below in "Agency Contacts." All correspondence requires the signature of an authorized business official and/or the project director. Failure to follow this guidance will result in a delay in responding to your correspondence. (4) The DHHS Appropriations Act requires that, when issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, the issuance shall clearly state the percentage and dollar amount of the total costs of the program or project that will be financed with Federal money and the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

*3. Reporting:* A successful applicant will submit an annual technical report and a Financial Status Report in accordance with provisions of the general regulations which apply under "Monitoring and Reporting Program Performance," 45 CFR parts 74 and 92. An original and two copies of the annual report must be submitted by August 15. The annual report will serve as the non-competing continuation application and must cover all activities for the entire budget year. Therefore, this report must also include the budget request for the next grant year, with appropriate justification, and signatures, and be submitted using Form OPHS-1. A Financial Status Report (FSR) SF-269 is due 90 days after the close of each 12-month budget period.

**VII. Agency Contact(s)**

For application kits and information on budget and business aspects of the application, please contact: Office of Grants Management, Office of Public Health and Science, Department of Health and Human Services, 1101

Wooten Parkway, Suite 550, Rockville, MD 20857. Telephone: (240) 453-8822.

Questions regarding programmatic information and/or requests for technical assistance in the preparation of the grant application by CCOEs should be directed in writing to Ms. Barbara James, Director, National Community Centers of Excellence in Women's Health Program, 5600 Fishers Lane, Room 16A-55, Rockville, MD 20859. Telephone: (301) 443-1402. E-mail: [bjames1@osophs.dhhs.gov](mailto:bjames1@osophs.dhhs.gov). Questions from the CoEs should be directed to Ms. Eileen Newman, Public Health Analyst at the same address. Her e-mail is [enewman@osophs.dhhs.gov](mailto:enewman@osophs.dhhs.gov).

#### VIII. Other Information

Eleven (11) CCOE programs and three (3) CCOE Ambassador for Change programs are currently funded by the OWH. Information about these programs may be found at the following Web site: <http://www.4woman.gov/owh/CCOE/index.htm>.

Seventeen (17) CoE programs and three (3) CoE Ambassadors for Change programs are currently funded by the OWH. Information about these programs may be found at the following Web site: <http://www.4woman.gov/COE/index.htm>.

Dated: March 16, 2006.

**Wanda K. Jones,**

*Deputy Assistant Secretary for Health (Women's Health), Office of Public Health and Science.*

[FR Doc. E6-4188 Filed 3-22-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2000E-1252] (formerly Docket No. 00E-1252)

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ALAMAST 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 Division of Dockets Management (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 V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6681.

**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 approved for marketing the human drug product ALAMAST (pemirolast potassium). ALAMAST is indicated for the prevention of itching of the eye due to allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ALAMAST (U.S. Patent No. 5,034,230) from Santen Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated

April 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ALAMAST 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 ALAMAST is 1,298 days. Of this time, 1,115 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* March 7, 1996. The applicant claims March 6, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 7, 1996, 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 of the act:* March 26, 1999. The applicant claims March 25, 1999, as the date the new drug application (NDA) for ALAMAST (NDA 21-079) was initially submitted. However, FDA records indicate that NDA 21-079 was submitted on March 26, 1999.

3. *The date the application was approved:* September 24, 1999. FDA has verified the applicant's claim that NDA 21-079 was approved on September 24, 1999.

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, this applicant seeks 755 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 22, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 19, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess.,