

trigger the accommodate or explain rule. A list of the Single Points of Contact for each State and Territory can be found on line at <http://www.whitehouse.gov/omb/grants/spoc.html>.

Dated: April 25, 2001.

Gail E. Collins,

Acting Deputy Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF/HS-2001-10]

Fiscal Year 2001 Discretionary Announcement for Head Start—Higher Education Hispanic/Latino Service Partnerships: Availability of Funds and Request for Applications

AGENCY: Administration on Children, Youth and Families (ACYF).

ACTION: Notice.

Statutory Authority: The Head Start Act, as amended 42 U.S.C. 9801 *et seq.*

SUMMARY: The Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF) announces the availability of approximately \$500,000 annually for each of four (4) years to support Head Start-Higher Education Hispanic/Latino Service Partnerships (HS-HEHLSPs). The goal of this HS-HEHLSPs initiative is to improve the quality and long term effectiveness of Head Start and Early Head Start programs by developing models of academic training through partnerships between institutions of higher education and Head Start and Early Head Start agencies. The priority for this funding is: Partnerships to increase the number of center-based teachers with AA, BA or advanced degrees in early childhood education or related fields earned by Head Start teachers, in order to assist Head Start grantees to meet the 2003 Congressional mandate and to provide teachers with knowledge areas vital in building quality Head Start programs.

DATES: The closing date and time for receipt of application is 4:30 p.m. (Eastern Time Zone), June 15, 2001.

Note: Applications should be submitted to: ACYF Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, Virginia 22209.

However, prior to preparing and submitting an application, in order to

satisfactorily compete under this announcement, it will be necessary for potential applicants to read the full announcement which is available through the addresses listed below.

ADDRESSES: Applications, including all necessary forms can be downloaded from the Head Start Web site at www.acf.dhhs.gov/programs/hsb. The Web site also contains a listing of all Head Start and Early Head Start programs. Hard copies of the application may be obtained by writing or calling the Operations Center or sending an e-mail to hhs@lcnnet.com.

FOR FURTHER INFORMATION CONTACT:

ACYF Operations Center at: 1815 N. Fort Myer Drive, Suite 300, Arlington, Virginia 22209 or 1-800-351-2293.

SUPPLEMENTARY INFORMATION:

Eligible Applicants: Institutions of higher education with experience and capability in educating and preparing professionals to work effectively with Hispanic young children and families are eligible to apply. Institutions that are currently funded under the Head Start—Higher Education Hispanic Service partnerships are not eligible to apply under this announcement.

Project Duration: The announcement is soliciting applications for project periods up to four years. Awards, on a competitive basis, will be for a one-year budget period, although projects may be for four years. Applications for continuation funds under these awards beyond the first year budget period, but within the established project period, will be entertained in subsequent years on a non-competitive basis, subject to availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the Government.

Federal Share of Project Costs: The maximum share is \$150,000 for the first year of the four-year period. The Federal share is inclusive of indirect costs.

Matching Requirements: There are no matching requirements.

Anticipated Number of Projects to be Funded: It is anticipated that approximately four projects will be funded.

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Review Criteria

Criterion 1. Objectives and Need for Assistance: (10 Points)

The extent to which the application identifies relevant physical, economic, social, financial, institutional or other problems requiring a grant;

demonstrates the need for assistance; and states the principal and subordinate objectives of the project consistent with the purposes of the program announcement.

The Head Start Bureau is particularly interested in the following aspects of the applications:

1. State the specific training objectives for the program. Indicate how these objectives are based on an assessment of staff training and program improvement needs of participant Head Start and Early Head Start agencies; how they related to Head Start goals, outcomes and policy priorities, and how they will enhance the quality of Head Start services to Hispanic/Latino children and their families.

2. Describe the process used to assess the needs for the proposed program design. Specifically identify the population to be served in terms of numbers and types of staff to be trained and the proposed areas of training, course, and/or degrees to be awarded.

3. Describe the development of the HS-HEHLSPs agreement and other consultation related to the development of the proposed initiative. Describe any efforts to frame the proposed initiative within broader state or community efforts to enhance professional and career development for staff in all forms of early childhood and child care programs.

Criterion 2. Results or Benefits Expected: (20 points)

The extent to which the application identifies the results and benefits to be derived; describes the anticipated contribution to policy, practice, theory and/or research; specific benefits should be described for both the HS-HEHLSPs and Head Start/Migrant Head Start/Early Head Start partners.

The Head Start Bureau is particularly interested in the following aspects of the applications:

1. Based on the stated program objectives, identify the results and benefits to be derived. Identify the specific results or benefits that could be expected for the Head Start grantee(s) and the institution. Describe how the trainees benefit from the project.

2. Identify both qualitative and quantitative data the applicant will collect to measure progress towards the stated results or benefits. Identify how the program will determine the extent to which it has achieved its stated objectives.

3. Provide a projection of the estimated number of trainees, by category, who will earn degrees over the four year duration of the project based on an analysis of the current levels of

credits/courses earned by participants and a proposed sequence of courses.

Criterion 3. Approach (40 points)

A. The extent to which the application outlines a sound and realistic plan of action pertaining to the scope of the project which details how the proposed work will be accomplished, including a timeline; lists of each organization, consultants, including the evaluator, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution; and assures the adequacy of time devoted to the project by key staff;

B. The extent to which the project approach, if successfully carried out, is likely to achieve the proposed project objectives; and

C. The applicant must fully describe the approach and/or methodology and delineate the relationship of each task to the accomplishment of the proposed objectives. There should be evidence that the planned approach reflects sufficient input from and partnership with Head Start/Migrant Head Start/Early Head Start and the HS-HEHLPs.

The Head Start Bureau is particularly interested in the following aspects of the applications:

1. Describe the planning the applicant will conduct during the start-up period to prepare for implementation of the program. Provide assurance that no more than six months will be devoted to planning activities.

2. Indicate how Head Start staff will be recruited and selected to participate in the program, including staff from other child care organizations that are collaborating with Head Start grantees and delegate agencies and meet Head Start performance standards within a given community.

3. Describe how the training and coursework will be contextually and culturally relevant to the Head Start, Migrant Head Start and the Early Head Start environment and how it will contribute to enhancing the effectiveness of teachers, staff, program quality and outcomes for Head Start children and families.

4. Describe efforts by the institution and Head Start partners to make training and coursework accessible to Head Start participants and to support their successful completion of courses, training, and degrees. Include a discussion of issues such as the timing, scheduling, and location of classes or training; support to enhance the literacy and study skills of participants; and approaches to integrate HS-HEHLPs training in the working environment of the Head Start program.

5. Describe efforts to complement the federal funds requested in this proposal with other resources to maximize the benefits to Head Start and HS-HEHLPs participants. Include any efforts or plans to assist Head Start staff in accessing sources of financial assistance or to make use of other funding for training and career development of early childhood program staff. In addition, describe any proposed contributions of funds from local Head Start programs to the partnership. Provide assurance that trainees will not be required to bear any costs of participating in training.

6. Describe how previous CDA training and certification of Head Start staff, as well as previous coursework, credits or AA degrees from 2-year institutions, will be linked to academic credits and course sequences leading to BA degrees.

7. Describe the organizational structure that will support the project objectives. Indicate how joint planning and assessment with the Head Start, Migrant Head Start and Early Head Start grantees will be implemented with timelines and clear lines of responsibility. Indicate how staff positions are assigned and describe their major functions and responsibilities.

8. Describe the activities that will continue after the completion of this project that will ensure that the institution will continue to participate in providing educational opportunities for Head Start, Migrant Head Start and Early Head Start staff.

9. Include support letters that document consultation and support from the proposed grantee or delegate agency partners, the Head Start Collaboration Office, and any existing state level early childhood career development initiative.

Criterion 4. Staff and Position Data (20 points)

Key staff should be qualified and knowledgeable of Head Start, Migrant Head Start and Early Head Start. The extent of the demonstrated capacity of the applicant organization, key leaders, managers and project personnel to:

1. provide high quality, relevant, and responsive training to Head Start staff;

2. assure participating project staff are competent to plan and deliver appropriate course material to Head Start trainees that is culturally relevant;

3. manage the implementation of the training grant in an effective and timely manner; and

4. manage successful partnership that involve sharing resources, staffing, and facilities.

Criterion 5. Budget and Budget Justification: (10 points)

The extent to which the project's costs are reasonable and appropriate in view of the activities to be carried out and the anticipated outcomes. Provide a line item detail for the costs of attendance of project staff to attend ACF-sponsored conferences in Washington, DC. It is the expectation that applicants should limit budget projections to those costs necessary to build institutional capacity for and execute training and career development partnerships with participating Head Start grantees.

Required Notification of the State Single Point of Contact

This program is covered under Executive Order 12372, Intergovernmental Review of Federal Programs, and 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, American Samoa and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-four jurisdictions need take no action regarding Executive Order 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of Executive Order 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 6a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. SPOCs are encouraged to eliminate the

submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodation or explain rule.

When comments are submitted directly to ACF, they should be addressed to: William Wilson, Head Start Bureau, 330 C Street, SW., Washington, DC 20447, Attn: Head Start-Higher Education Hispanic/Latino Service Partnerships. A list of the Single Points of Contact (SPOCs) for each State and Territory can be found on the following web site: <http://www.whitehouse.gov/omb/grants/spoc.html>.

Dated: April 25, 2001.

Gail E. Collins,

Acting Deputy Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0174]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's recall regulations (guidelines) and provides guidances to manufacturers on recall responsibilities.

DATES: Submit written or electronic comments on the collection of information by July 2, 2001.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA Recall Regulations—Part 7 (Subpart C) (21 CFR Part 7 (Subpart C))—(OMB Control Number 0910-0249)—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and 21

CFR part 7, subpart C sets forth the recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluating return reply cards, effectiveness checks and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2000. The resulting number of recalls from this database search (1,933) is used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the above information to 84,665 burden hours.

The following is a summary of the estimated annual burden hours for manufacturers, processors, and distributors to comply with the voluntary reporting requirements of FDA's recall regulations.

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates on average the burden of collection for recall information as follows: