

Certification Regarding Environmental Tobacco Smoke

Public Law 103-227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families**

[Program Announcement No. 93600-97-1]

Availability of Funds and Request for Applications Fiscal Year 1997 Discretionary Announcement for Cooperative Agreements To Support Head Start Quality Improvement Centers

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Announcement of the availability of fiscal year 1997 funds and request for applications for 16 multi-year Head Start Quality Improvement Centers to provide training and technical assistance to local Head Start projects.

SUMMARY: The Administration for Children and Families, Administration on Children Youth and Families' Head Start Bureau announces the availability of competitively awarded cooperative agreement grants to assist qualified institutions and organizations in the provision of training and technical assistance (T/TA) to local Head Start projects in 16 service areas. The cooperative agreements will support

Head Start Quality Improvement Centers (HSQICs). ACF Regions I, III, VII, VIII, IX, X, the American Indian Program and Migrant Program Branches will have one HSQIC each while ACF Regions II, IV, V, and VI will have two HSQICs. The States included in each of these 16 service areas are listed in Appendix A.

DATES: The closing date for receipt of applications under this announcement is June 9, 1997.

FOR FURTHER INFORMATION CONTACT: Questions related to the Program Announcement, please contact the ACYF Operations Center, Technical Assistance Team at 1-800-351-2293. Staff at this center will answer questions regarding the application requirements or refer you to the appropriate contact person in ACYF for programmatic questions. You may also locate frequently asked questions about this program announcement on the ACYF Website at <http://www.acf.dhhs.gov>.

Background and Program Purpose

Head Start is a national program that provides comprehensive developmental services for preschool children, ages three to five from low-income families and, under the Early Head Start program, for infants, toddlers and pregnant women. An essential feature of every Head Start program is the involvement of parents, both in the development of their children and in the direction of the program at the local level.

Now administered by the Administration for Children and Families, the Head Start program began in 1965 in the Office of Economic Opportunity as an innovative way to serve children and their low-income families. For FY 1997, \$3,981,000,000 is available for Head Start and approximately 752,000 children are expected to be enrolled. Approximately 1,430 community-based, public and private non-profit organizations receive Head Start grants and develop unique and innovative programs within a framework of national standards to meet their specific local needs. Head Start links families with other community institutions and local education agencies through both center and home-based programs.

In FY 1994 the Advisory Committee on Head Start Quality and Expansion issued its recommendations for improvement and expansion. It recommended that Head Start (1) Strive to achieve quality and excellence in every local Head Start program, (2) respond flexibly to the needs of the children served and their families and

(3) forge new partnerships at the community, State and Federal levels. The Committee found that most Head Start grantees provide high quality services; however, the quality of programs is uneven across the country.

In renewing the Head Start vision in a way that responds more effectively to a changing world, Head Start is continuing to provide high quality comprehensive services and to strive for excellence. As Head Start is expanding and renewing itself, there is a concomitant need for assistance from institutions and organizations that can provide effective and responsive training and technical assistance that support the work of the grantee and delegate agencies that directly provide the services to children and their families.

The Head Start Quality Improvement Centers (HSQICs) created through this announcement will form a regionally-based system, composed of institutions and organizations whose common purpose will be to work with local Head Start programs through training and technical assistance (T/TA). This nationwide T/TA effort is designed to support the continuous improvement of all grantees and delegate agencies as they work to provide high quality and effective services to children and families and address the emerging priorities of child care partnerships, Head Start expansion and welfare reform. The T/TA system reflects a national commitment to quality improvement, local capacity-building and ongoing evaluation.

In previous years, ACF operated its national Head Start T/TA system through contracts, acquiring the services of qualified providers to meet the training and technical assistance needs of local Head Start programs. In this announcement, ACF responds to the recommendations of the Secretary's Advisory Committee on Head Start Quality and Expansion and to consultations with more than 1,000 people in the field of Head Start and early childhood development to redesign its T/TA system. This cooperative agreement approach will provide assistance to institutions and organizations with expertise in the field of early childhood development and education to: Respond to the needs of grantees and delegate agencies and of communities for flexible technical assistance; expand the influence of Head Start as a national laboratory to other community- and academically-based early childhood programs; and to work with grantees and delegate agencies and with communities in

achieving continuous quality improvement of their services for children and low-income families. Rather than a system of T/TA that relies principally on Federal direction and decision-making, this new approach seeks to assist experts in the communities where Head Start programs provide services in becoming collaborators in a renewed quality improvement effort.

This revised Head Start T/TA system will promote excellence by supporting a continuous learning environment for Head Start staff. It will foster partnerships among Head Start programs, communities, academic institutions (two or four year colleges and universities) and governments to engage them in helping children, parents, and staff develop their full potential.

The HSQICs are to work with Head Start grantees to enable Head Start programs to develop the following capacities:

- Provide effective early childhood education programs that model a comprehensive child development approach;
- Enhance the quality of life and maximize the potential of Head Start-eligible children and their families;
- Identify and effectively access a wide variety of resources available to the grantees and delegate agencies, both within and outside Head Start;
- Integrate all of the component resources available to a Head Start program so as to enhance and reinforce a comprehensive approach to families and children;
- Establish and maintain linkages with the child care community to assure effective partnerships among providers of child development programs; and
- Maintain the unique qualities of Head Start and help sustain these qualities through periods of growth and change.

Among the services the HSQICs will provide are the following:

- Provide joint training opportunities with academic institutions for clusters of grantees that have the same needs based on an in-depth needs assessment.
- Interact with Head Start State Associations and American Indian and Migrant Head Start Associations, State agencies and community organizations to coordinate services and to track relevant State legislation and regulations.
- Focus upon management, coordination and facilitation of T/TA services within the Region or sub-Region.
- Enhance local program capacity to ensure continuous improvement.
- Establish and maintain a cadre of qualified, locally-based consultants to provide T/TA.
- Customize services based upon research and supported by state-of-the-art technology.
- Facilitate information sharing and collaboration with stakeholders in Head Start

and in the early child care communities as well as academic communities.

- Engage in an ongoing strategic planning process that will allow the system to adapt to a demanding and changing environment.

The HSQICs will each establish structures for the delivery of services that meet the needs of their service area. We expect these structures will vary from HSQIC to HSQIC. These structures might involve creating one or more satellite sites to serve the Head Start grantees in a State, in several States or a cluster of grantees in parts of one or more States. Such State or cluster sites may be used to establish a presence closer to grantee communities. Large States may have more than one cluster site and smaller States may share a cluster site. The American Indian Programs Branch's HSQIC may have up to three cluster sites and the Migrant Programs Branch's HSQIC may have up to two cluster sites. In other instances, a HSQIC might assign staff within its central office to serve as liaison to grantees in a State or part of a State. Applicants are encouraged to propose efficient and effective approaches to achieving this kind of geographic proximity.

It is assumed that Head Start grantees and delegate agencies will have varying levels of T/TA needs and will, therefore, seek varying levels of assistance from this project.

HSQICs will be responsible for fulfilling the program goals and objectives outlined in their applications, including responsibilities for directing, managing and implementing programs of training and technical assistance for the Regions that they serve. These programs should be tailored to meet the needs of the various Head Start grantees, the state of the field of early childhood, and the existing resources within the Region or sub-Region.

Additional information about the range of program areas and needs of Head Start grantees and guidance to approaches to training and technical assistance is provided in Appendix B.

Federal Involvement

Federal involvement in the HSQICs will include substantial roles for the Head Start Bureau, which includes the American Indian Programs Branch and the Migrant Programs Branch, and the ACF Regional Offices. Substantial Head Start Bureau and ACF Regional Office involvement with the HSQIC will occur when:

- Changes in initiatives or national Head Start policy need to be communicated to the HSQIC because of the effect on the Head Start programs with which the HSQICs are working;

- Federal approval is needed for the HSQIC to select or award a subgrant or contract;
- Federal consultation and approval is needed in the selection of a project director;
- Federal collaboration or joint planning and participation in conferences or meetings with Head Start programs and child development professionals will achieve efficiencies and more effective agendas; and
- Participation on the HSQIC's Regional T/TA Coordinating Council with others, as described in Appendix B, will assist the HSQIC provider in setting overall policies and in conducting an ongoing evaluation of the T/TA provided.

The roles of the Head Start Bureau and ACF Regional Offices are as follows: The Head Start Bureau will:

- Provide leadership and support for the national Head Start T/TA system, which includes the use of national contractors and HSQICs to support meetings, program monitoring, materials development and other specific needs;
- Set Head Start program priorities and formulate new initiatives that may affect the plans and priorities of the HSQICs, and consult regularly with the HSQICs to ensure that they are fully informed of these national priorities and initiatives;
- Set standards for the HSQICs in the provision of quality Head Start T/TA services for children and families;
- Foster collaboration within and outside of Head Start, develop partnerships among Federal programs, and promote partnerships with the business community;
- Conduct semiannual T/TA meetings, to which the HSQICs will be invited; and
- Monitor the HSQICs to ensure accountability and fiscal responsibility throughout the T/TA system.

The ACF Regional Offices and the Head Start Bureau's American Indian Programs Branch and Migrant Programs Branch will each:

- Appoint a T/TA coordinator to coordinate Regional or sub-Regional T/TA services and to serve as a liaison with the HSQIC;
- Participate in the HSQIC's Regional or sub-Regional Coordinating Council, as described in Appendix B;
- Review a summary of the needs assessments and the T/TA plans for grantees in the Region or sub-Region in order to effectively coordinate T/TA activities;
- Conduct bimonthly (every other month) conference calls or Regional or sub-Regional T/TA coordinating meetings;
- Attend national T/TA meetings;
- Seek out collaborations within and outside the Head Start program by participating on the HSQIC's Regional or sub-Regional Coordinating Council; exhibiting leadership in coordinating child care/Head Start partnerships and working with the Head Start State Collaboration grantees;
- Annually review all services performed by the Regional HSQIC prior to submission of the continuation application in order to provide relevant consultation to the HSQIC and Regional or sub-Regional coordination;

- Conduct reviews and manage the follow-up process for deficient grantees, i.e., carry out joint planning with the HSQIC designed to address identified deficiencies and to identify the T/TA needed by deficient grantees in order to implement their Quality Improvement Plans (QIPs); and
- Encouraging well-performing grantees to develop their own T/TA plans and to implement their own T/TA.

Program Duration

This announcement is soliciting applications for project periods up to five years. Awards, on a competitive basis, will be for a one-year budget period. Applications for continuation cooperative agreements funded under these awards beyond the one-year budget period, but within the five-year project period, will be entertained in subsequent years on a noncompetitive basis, subject to the availability of funds, satisfactory progress of the cooperative agreement grantee and a determination that continued funding would be in the best interest of the government.

Eligible Applicants

Public, private nonprofit, and private for-profit organizations are eligible to apply for these cooperative agreements. It should be noted that for-profit organizations must waive their fee/profit.

Only incorporated agencies and organizations, not individuals, are eligible to apply. On all applications developed jointly by more than one agency or organization, the application must identify only one organization as the lead organization and the official applicant. The other organizations may be included as participants, subgrantees or subcontractors.

Before the applications are reviewed, each application will be screened to determine that the applicant organization is an eligible applicant as specified. Ineligible applicants will be notified at that time.

Project Development

Applicants are urged to discuss their interests and ideas for developing HSQICs early in the planning stage with local Head Start grantees and appropriate State, Regional, and local agencies. Community support should be encouraged by providing opportunities for public and private participation in the planning and development phases.

This program is covered under Executive Order 12372, "Intergovernmental Review of Federal Programs," and 45 CFR Part 100, "Intergovernmental Review of Health and Human Services Program and Activities."

Under the Executive Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. All jurisdictions which participate in the Executive Order process have established Single Points of Contact (SPOCs). A list of the Single Points of Contact for each State and Territory is included in this program announcement as Appendix C. Applicants from participating jurisdictions should contact their SPOCs as soon as possible to alert them to the prospective applications and to receive instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the ACF program office can obtain and review SPOC comments as part of the award process. The applicant must 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 16a. Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new and 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 "accommodate or explain" rule. When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Head Start Bureau, Administration on Children, Youth and Families, P.O. Box 1182, 330 C Street, S.W., Washington, D.C. 20201.

Completing the Application

In preparing the application, use standard English language and avoid jargon. For the program narrative, type using black print no smaller than 12 pitch or 12 point size. An application may not exceed 250 double-spaced pages inclusive of resumes, charts and appendices. If applications exceed 250 double-spaced pages, the other pages will be removed from the application and not considered by the reviewers.

Each copy should be secured with a binder clip in the upper left-hand corner. The application must be paginated beginning with the Standard Form 424 (SF-424) and also contain a table of contents listing each section of the application with the respective pages. To facilitate handling, do not use covers, ring binders or tabs. Applicants are requested not to send pamphlets, brochures, or other printed materials as these pose xeroxing difficulties nor

should any video material be submitted. These materials, if submitted, will not be included in the review process if they exceed the page limitation. Each page of the application will be counted to determine total length. Applicants are advised that the copies of application submitted, not the original, will be reproduced by the Federal government for review.

Instructions for completing the forms are found either on the reverse sides of the forms or on supplemental pages.

Additional guidance may be provided in the program announcement. If more space is needed than is provided, use a blank sheet of paper to complete the item, using the identical format. Clearly identify the continuation page as such, and the information items contained thereon, and attach the page after the appropriate page of the application. Computer-generated facsimiles may be substituted for any of the forms provided in this packet. Such substitute forms should be printed in black ink and must maintain the exact wording and format of the government-printed forms, including all captions and spacing. Any deviations may be grounds for ACF to reject the entire application.

Additional note: For SF-424 item "Federal Identifier," if the applicant organization currently has a payment account with the Department of Health and Human Services, cite the Payee EIN or PIN in the "Federal Identifier" block.

Assembling

To facilitate the review and processing of the application by the awarding office, all pages should be numbered and preceded by a table of contents. Assemble the application with the cover letter (if provided) on top followed by a table of contents, the SF-424 series forms, the program narrative, and any remaining documents. Completed applications should be signed and dated in ink by the authorized official of the applicant organization. An original and two copies of the application should be provided. Applicants may omit from the application copies which will be made available to the non-Federal reviewers that specify salary rates or amounts for individuals identified in the application budget. Rather, only summary information is required.

Applicants are encouraged to use the least costly, but most efficient method for binding and securing their application documents.

Application Submission

Mail or hand deliver completed applications in accordance with the instructions in this announcement. Be

aware that the deadline specified in this announcement is either a 'receipt date' or a 'postmark date' deadline. Also note that there are different instructions and addresses for mail delivery and hand delivery of applications. ACF cannot accommodate transmissions of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

An applicant should submit an original and two copies of its application by mail to: ACYF Operations Center, 3030 Clarendon Blvd., Room 240, Arlington, Virginia 22201, (703) 351-7676, (703) 528-0716 (FAX).

An applicant may apply for more than one Regional or sub-Regional service area, but must submit a separate application for each service area for which it is applying.

Applications hand-carried by applicants, applicant couriers, or by overnight/express mail couriers shall be considered as meeting an announced deadline date if delivered between the normal working hours of 8 a.m. and 4:30 p.m., to Room 240, 3030 Clarendon Blvd., Arlington, Virginia, Monday through Friday, (excluding Federal holidays). (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

The closing date for the submission of applications under this announcement is June 9, 1997.

Deadlines: Applications will be considered as meeting the above deadline if they are either:

1. received on or before the deadline date at the receipt point specified in this program announcement, or
2. sent on or before the deadline date and received by ACF in time for the independent review.

Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that applications are received on or before the deadline date.

Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Late Applications

Applications which do not meet the criteria above are considered late applications. ACF will notify each late applicant that its application will not be considered in the current competition.

ACF may extend the deadline for all applicants because of acts of God such as floods, hurricanes, etc., or when there is a widespread disruption of the mails. However, if ACF does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicants.

Intent To Apply

If you are going to submit an application, send a postcard or call in the following information: the name, address, and telephone number of the contact person; the name of the organization; and the Regional or sub-Regional service area in which you may submit an application within two weeks of receipt of this announcement to: Administration on Children, Youth and Families, Operations Center, 3030 Clarendon Boulevard, Room 240, Arlington, Va. 22201. The telephone number is 1-800-351-2293. This information will be used to determine the number of expert reviewers needed and to update the mailing list of persons to whom the program announcement is sent.

Acknowledgement of Receipt

Each applicant will be sent a written acknowledgement of receipt by ACF as soon as possible after receipt of an application. Applicants are welcome to provide a mailing label with their application to help expedite this process. If provided, the mailing label should reflect the mailing address of the authorizing official who is applying on behalf of the organization. If acknowledgment of receipt of your application is not received within eight weeks after the deadline date, please notify the ACYF Operations Center by telephone at 1-800-351-2293.

Nonconforming Applications

Applications which are determined to be nonconforming shall not be accepted for processing and shall be returned to the applicant. A grant application may be classified as nonconforming if it does not meet the requirements of this program announcement.

Application Review

Applications will be evaluated and rated according to criteria and priorities which are established for the particular grant program involved and which are described in this announcement (see below).

ACF anticipates awarding cooperative agreements for the T/TA grants described in this announcement. A cooperative agreement is a financial assistance award that allows substantial Federal involvement in the activities

undertaken with Federal financial support. Supporting the HSQICs through cooperative agreements will ensure cooperation and coordination in the provision of T/TA to Head Start programs and related community child development efforts between the Federal government and the organizations and institutions that operate HSQICs.

Timely applications from eligible applicants will be reviewed and scored competitively. Experts in the field, generally persons from outside the Federal government, will use the evaluation criteria listed below to review and score the applications. The results of this review are the primary factor in making funding decisions. ACYF may also solicit written comments from ACF Regional Offices, the Head Start Bureau and other Federal agencies with knowledge of the applicant's capability and expertise. These comments, along with those of the expert reviewers, will be considered in making funding decisions and will be a part of the official application file.

The applicant must demonstrate capacities to work with community-based, family-centered programs, low-income families, and the public and private organizations that relate to them. There must be a congruence of the applicant's mission or purpose with the basic mission of the Head Start program to provide comprehensive child development services for the children of low-income families.

Evaluation Criteria

All timely applications from eligible applicants will be evaluated on the extent to which they meet the following criteria:

a. *Objectives and Need for Assistance* (10 points) The applicant clearly and concisely identifies and documents relevant economic, social, financial, institutional and other problems requiring training and technical assistance; and states the principal and subordinate objectives of the proposed HSQIC. Supporting documentation or other testimony from concerned interests other than the applicant on the need for assistance may be used.

b. *Results or Benefits Expected* (10 points) The applicant clearly and concisely identifies the specific and measurable results and benefits to be achieved by the proposed HSQIC, which are consistent with the objectives of the proposal, and indicates anticipated contributions to the quality of Head Start services, policy, and practice.

c. *Approach* (40 points) The applicant describes how the project will be conducted. The applicant describes: How grantees will be supported in moving toward higher levels of quality and excellence; the levels of training and technical assistance service that will be provided to different categories of

grantees and how grantees will be selected for each level of service; the uses that will be made of communication technology and learning modules; how priorities will be set among competing demands; and how work assignments will be managed. The applicant proposes a realistic and comprehensive plan of action for achieving the objectives of the proposed HSQIC; details how the proposed training and technical assistance would be accomplished and lists organizations, consultants, and other key individuals who will work on the project; and describes its approach to ensuring continuous improvement in its efforts to meet the identified needs and to achieve the identified results and benefits.

d. *Staff Background and Organization's Experience* (20 points) The applicant identifies qualified staff with the necessary educational and experiential backgrounds and documents the background of the proposed project director and other proposed project staff (providing name, address, training, most relevant educational background and other qualifying experiences along with resumes and short descriptions of their proposed responsibilities or contributions to the applicant's work plan); the experience of the applicant in administering a project like the one proposed; and the applicant's ability to effectively and efficiently administer this project.

e. *Budget Appropriateness and Reasonableness* (20 Points) The applicant clearly describes and justifies as reasonable and realistic the project's costs in view of the activities to be carried out and the anticipated outcomes.

Funding Decisions

After a decision has been reached to disapprove or not fund a grant submission during a given review cycle, a written notice shall be sent to the unsuccessful applicant by the responsible program official within 30 days after that decision.

After Federal funds are exhausted for a grant competition, applications which have been independently reviewed and ranked but have no final disposition (neither approved nor disapproved for funding) may again be considered for funding. Reconsideration may occur at any time funds become available within 12 months following ranking. ACF does not select from multiple ranking lists for a program. Therefore, should a new competition be scheduled and applications remain ranked without final disposition, applicants are informed of their opportunity to reapply for the new competition, to the extent practical.

The anticipated annual funding for the HSQICs will range from a minimum of approximately \$775,000 to a maximum of approximately \$2,400,000, depending upon the service area. These amounts are generally proportionate to a combination of the number of Head

Start children and the number of Head Start grantees in each service area, as compared to other service areas. Below is a list of the projected annual funding level for the initial funding year for each service area. It is anticipated that funding for each of the four possible subsequent years of funding will, at a minimum, equal the funds available for the first year.

Service areas	Number of grantees in service area	Estimated funding
Region I	80	\$1,164,170
Region II(a)	92	1,718,000
Region II(b)	14	778,050
Region III	146	1,970,700
Region IV(a)	118	1,711,000
Region IV(b)	115	2,330,000
Region V(a)	88	1,519,000
Region V(b)	125	2,188,500
Region VI(a)	86	1,431,490
Region VI(b)	94	1,656,000
Region VII	73	1,204,350
Region VIII	75	1,273,390
Region IX	79	2,374,520
Region X	64	922,040
American Indian Programs	130	1,512,500
Migrant Programs	25	1,696,290

Program income must be reported to ACF, and its use, accounted for on the SF 269, must enhance the ACF cooperative agreement projects and benefit the Head Start grantees. The income must be added to funds committed to the cooperative agreement and must be used to further eligible program objectives. There is no requirement to request prior approval to defer the use of program income for a later period of time.

It is anticipated that eight Regional and eight sub-Regional HSQICs will be funded under this announcement. ACYF intends to award the new cooperative agreements under this announcement during the third or fourth quarters of FY 1997.

Program Narrative

The program narrative provides a major means by which the application is evaluated and ranked to compete with other applications for available assistance. It should be concise and complete and should address the activity for which Federal funds are being requested. Supporting documents should be included when they can present information clearly and succinctly. Applicants are encouraged to provide information on their organization structure, staff, related experience, and other information considered to be relevant. Awarding offices use this and other information to

determine whether the applicant has the capability and resources necessary to carry out the proposed project. It is important, therefore, that this information be included in the application. However, in the narrative, the applicant must distinguish between resources directly related to the proposed project and those which will not be used in the support of the specific project for which funds are being requested.

Cross-referencing should be used rather than repetition. ACF is particularly interested in specific factual information and statements of measurable goals in quantitative terms. Narratives are evaluated on the basis of substance, not length. Extensive exhibits are not required. (Supporting information concerning activities which will not be directly funded by the grant or information which does not directly pertain to an integral part of the grant funded activity should be placed in an appendix.) Pages should be numbered for easy reference.

Prepare the program narrative statement using the following format and guidance:

1. *Project Summary/Abstract.* A summary of the project description (usually a page or less) with reference to the funding request should be placed directly behind the table of contents or SF-424.

2. *Objectives and Need for Assistance.* Applicants must clearly identify the physical, economic, social, financial, institutional or other T/TA problems requiring solutions. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referenced in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the narrative, the applicant is requested to provide information on the total range of projects currently conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

3. *Results or Benefits Expected.* Identify the results and benefits to be derived from the T/TA services to be provided.

4. *Approach.* Outline a plan of action that describes the scope and detail of how the proposed work would be accomplished. Account for all functions or activities identified in the

application. Cite factors which might accelerate or decelerate the work and state your reasons for taking your approach rather than others.

Describe unusual features of the project such as use of technological innovations, reductions in costs or time, or extraordinary social and community involvement.

Successful applicants will present approaches for providing training and technical assistance to Head Start programs that take into account that some grantees and delegate agencies may have self-sufficient, well-developed and multifaceted T/TA efforts, while other grantees and delegate agencies may have a greater need for T/TA from Regionally-based providers. Additional guidance on project design is provided in Appendix B.

Describe the approaches to be taken and the issues taken into consideration for establishing close working relationships at State levels or with geographically defined clusters of grantees.

Describe how the T/TA services would be designed for or could be adapted for local Head Start programs in a variety of settings including center-based, home-based, combination, part- and full-day programs.

Describe a strategy for working in cooperation with the ACF Regional Office responsible for the service area in which the application proposes to provide T/TA or with the American Indian Program Branch and Migrant Programs Branch, respectively.

5. *Geographic Location.* Give the precise location of the HSQIC and/or State/cluster sites and the boundaries of the area to be served by the proposed project. Maps or other graphic aides may be attached.

6. *Additional Information.* Staffing and Position Data—Provide biographical sketches for key personnel proposed and a job description for each vacant key position.

Organization Profiles—Describe your institutional/organizational capability and background in early childhood development/early childhood education, Head Start programs, child care, family support, community building, higher education/training and T/TA delivery.

Include information on applicant organizations and their cooperating partners such as organizational charts, financial statements, audit reports or statements from a CPA/Licensed Public Accountant, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers for chief organizational officer(s).

Any nonprofit organization submitting an application must submit proof of its nonprofit status in its application at the time of submission. The nonprofit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS code or by providing a copy of the currently valid IRS tax exemption certificate, or by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

For profit organizations submitting an application must include a written statement which certifies that they operate as a corporation incorporated under the laws of the State of [fill in the blank], and must provide proof of this status."

Third-Party Agreements—Provide written agreements between grantees and subgrantees or subcontractors or other cooperating entities. These agreements may detail scope of work, work schedules, remuneration, and other terms and conditions that structure or define the relationship.

Letters of Support—Provide statements from community, public and commercial leaders who support the project proposed for funding.

Reporting—Provide quarterly progress reports for seriously deficient grantees, and describe how they were generated and coordinated with the Federal Project Officer and the Regional Coordinator i.e., quarterly statistics on: the number of on-site T/TA visits, the number of conferences/workshops, the number of local T/TA resources accessed, the number of child care programs receiving T/TA services.

Provide a quarterly financial statement which includes information on the amount of funds expended during the quarter, the cumulative amount expended, and the amount of funds remaining available.

Note: Eligible applicants must submit a complete application including the required forms included at the end of this program announcement.

In order to be considered for a cooperative agreement under this announcement, an application must be submitted on the forms and follow the directions provided in this announcement, all of which are approved by the Office of Management and Budget under Control Number 0970-0139. Required forms include the Standard Form 424 application form and Standard Form 424B, "Assurances: Non-Construction Programs."

Applicants must provide a certification concerning lobbying on the form provided (OMB-0348-0046). Prior to receiving an award in excess of \$100,000, applicants shall furnish an executed copy of the lobbying certification. Applicants must sign and return the certifications with their application.

Applicants must make the appropriate certification of their compliance with the Drug-Free Work Place Act of 1988. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicants must make the appropriate certification that they are not presently debarred, suspended or otherwise ineligible for award. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicants must also understand that they will be held accountable for the smoking prohibition included within P.L. 103-227, The Pro-Children's Act of 1994. A copy of the **Federal Register** notice which implements the smoking prohibition is included with the forms.

Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (Pub. L. 104-13), the Department is required to submit to the Office of Management and Budget (OMB) for review and approval any reporting and record-keeping requirement or program announcements. This program announcement meets all information collection requirements approved for ACF grant applications under OMB Control Number 0970-139.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Additional Information To Assist Applicants in Preparing Their Applications

For an information kit which identifies the Head Start grantees in each Regional and sub-Regional service area and which includes a copy of the revised Head Start Performance Standards, a copy of the Head Start regulations and other materials that may be useful in preparing of a response to this announcement, please contact: ACYF Operations Center, 3030 Clarendon Blvd., Suite 240, Arlington, Virginia 22201, 703-351-7676, 703-528-0716 (FAX).

Six information sharing meetings will be conducted in person or via video-

conference in the following locations and at the following times: (Please call the telephone numbers below for information about exact time and place):

- Washington, D.C., Switzer Building, Room 2100, 330 C Street, S.W., Contact: Rosalind Dailey, (202) 205-8347.
- New York, NY, ACF Region II, (212) 264-2974.
- Atlanta, GA, ACF Region IV, (404) 331-2398.
- Chicago, IL, ACF Region V, (312) 353-8322.
- Dallas, TX, ACF Region VI, (214) 767-9648.
- San Francisco, CA, ACF Region IX, (415) 437-8481.

The questions and responses discussed at these meetings will be shared with all participating parties as well as organizations expressing an interest in receiving copies.

Statutory Authority: Catalog of Federal Domestic Assistance (CFDA) number 93.600.
Dated: March 31, 1997.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

Appendix A—Regional and Sub-Regional Service Areas To Be Served by Individual Head Start Quality Improvement Centers

Region I Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Region II

Sub-region (a): New Jersey, New York

Sub-region (b): Puerto Rico, Virgin Islands

Region III Delaware, Maryland, Pennsylvania, Virginia, Washington, D.C., West Virginia

Region IV

Sub-region (a): Kentucky, North Carolina, South Carolina, Tennessee

Sub-region (b): Alabama, Florida, Georgia, Mississippi

Region V

Sub-region (a): Michigan, Minnesota, Wisconsin

Sub-region (b): Illinois, Indiana, Ohio

Region VI

Sub-region (a): Arkansas, Louisiana, Oklahoma

Sub-region (b): New Mexico, Texas

Region VII Iowa, Kansas, Missouri, Nebraska

Region VIII Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

Region IX Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Marianas, Guam, Trust Territories

Region X Idaho, Oregon, Washington; and a satellite center located in Alaska, serving both Region X and American Indian Program grantees.

American Indian Programs Branch

American Indian Head Start grantees in Alaska, Arizona, California, Colorado, Florida, Idaho, Kansas, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, New

York, North Carolina, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, Wisconsin, Wyoming
Migrant Programs Branch

Migrant Head Start grantees in Alabama, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, New Jersey, New Mexico, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin

Appendix B—Guidance for the Project Design of a Head Start Quality Improvement Center

The Regional or sub-Regional Head Start Quality Improvement Centers (HSQICs) are envisioned to be coordinator/information hubs at the Regional/American Indian Programs Branch (AIPB)/Migrant Programs Branch (MPB) level, disseminating and collecting information from the ACF Regional and National Offices, the American Indian Programs and Migrant Programs Branches, and Head Start grantees, as well as the broader child care community. The HSQICs are encouraged to work with local agencies to develop interagency agreements and partnerships for the delivery of T/TA.

As partners with the Head Start Bureau and ACF Regional Offices, the recipients of these awards are encouraged to propose plans that define strategies to meet the needs of Head Start grantees and delegate agencies as well as the child development field in the areas that they will serve. The strategies should provide for some level of support for all grantees and delegate agencies. The provision of T/TA should begin with a strategic planning process that will include a needs assessment and plan development and will continue with steps for the implementation of T/TA services and for the evaluation of those services. Information may be shared among the HSQICs and with the Head Start Bureau and ACF Regional Offices.

The HSQICs will have responsibility for assuring T/TA that can be provided statewide and to clusters of grantees, as well as to individuals at the grantee level. The HSQICs may consider the development of State/cluster sites. The State/cluster sites, suggested to ACF in consultations carried out in the preparation of this program announcement, are envisioned as extensions of the HSQICs. The number of skilled staff located at the State/cluster site would be dependent upon the size and number of grantees and delegate agencies and within the geographic area covered. Current teaching centers or State/American

Indian/Migrant Head Start Association offices might be considered as possible State/cluster sites.

In addition, the Regional and sub-Regional HSQICs should work with the ACF Regional Offices, the American Indian Programs and Migrant Programs Branches to implement T/TA in the following areas:

- Quality improvement:
 - * Core Head Start Services
 - + T/TA resources needed to assure compliance with the Head Start Program Performance Standards in each content area and to implement program improvement plans and best practices.
 - + Needs Assessments using information collected, analyses and syntheses from National Head Start T/TA providers, the Head Start Bureau and ACF Regional Offices, State/cluster sites and local Head Start grantees themselves.
 - + Regional or sub-Regional training based on needs assessments and emerging priorities shared by many grantees.
 - + Short- and long-range Regional T/TA plans developed by the Regional Coordinating Council, based on assessments, national and Regional program improvement plans, State/cluster information and national initiatives.
 - + Model evaluation plans for grantees and States/clusters to obtain assessments of the quality and effectiveness of T/TA services provided on-site, in workshops, and in direct consultation and the use of the evaluation data in planning future T/TA activities.
 - + Assistance to grantees in developing and implementing T/TA funded directly to Head Start grantees by Program Account #20 and other funds.
 - + In collaboration with the American Indian Programs and the Migrant Programs Branches, T/TA especially directed to meet the needs of American Indian and Migrant grantees for information on relevant Regional/State issues, regulations, and available resources or services.
 - + Emerging literacy and numeric development through materials and activities according to the developmental level of each child.
 - * Early Head Start (EHS)
 - + Collaboration with the Early Head Start-National Resource Contract (EHS-NRC) to enhance and reinforce a comprehensive approach to meeting the multiple needs of pregnant women, and families with infants and toddlers.
 - + Assistance in ensuring that EHS child and family development program models provide early opportunities for infants and toddlers to grow and develop in warm, nurturing and inclusive settings.
 - + State and Regional networks for the exchange of models, strategies and materials on partnership approaches to the funding and delivery of high quality, comprehensive early childhood services among and across Head Start grantees, child care centers and homes, school-based early childhood programs and other providers and settings serving young children and families.

- + Assistance to EHS programs to identify and assess a wide variety of resources available in communities.

- + Assistance to EHS programs to ensure continuous learning opportunities for training, supervision and mentoring in response to the ongoing development of new knowledge across disciplines and to enable the staff to recognize and respond to the best practices, lessons learned and quality goals of EHS.

* Child Development Associate (CDA) Certification

- + Assistance to grantee and delegate agencies to locate staff training with academic credit, as feasible, to help ensure:

- renewal of CDA credentials;
- qualified staff as defined in the Head Start Program Performance Standards, including teachers of infants and toddlers and teachers of preschool age children;
- + Assistance to grantee and delegate agencies in identifying qualified and experienced experts capable of providing on-site training and mentoring to teachers of infants and toddlers, teachers of preschool age children, home visitors, and family child care providers, and their respective supervisors over substantial periods of time.

- + Assistance to grantee and delegate agencies in implementing a curriculum suitable for the ages and stages of development of the children served which is consistent with the definition in the Head Start Program Performance Standards.

- + Identification of training resources and consultants to implement CDA requirements for home-based programs.

* Quality Improvement Plans and Monitoring Follow-up

- + Assistance to grantees found to be deficient to ensure that Quality Improvement Plans (QIPs) are implemented and identified deficiencies addressed, at the grantee's request.

- + Use of information from monitoring reviews, Program Information Reports (PIR), and data provided by the ACF Regional Office, the American Indian Programs and the Migrant Programs Branches to plan T/TA for grantees.

- + Development of procedures for grantees to communicate their special needs for T/TA to their Regional or sub-Regional and cluster coordinators.

In providing T/TA in the above-outlined areas, HSQICs may use the following approaches:

- Forms of collaboration and assistance
- * On-site collaboration/assistance
- + On-site T/TA in response to needs identified during the needs assessment process.
- + Special projects to meet Regional or sub-Regional service area needs.

- * Workshops and conferences
- + Regional or sub-Regional training workshops and institutes for grantees on Head Start-specific topics and other topics as determined by need, including fiscal management, management training (strategic long-range planning, communication systems, organizational structure, systems theory and program self-assessment), the Head Start Financial Information System

(HSFIS), Program Information Report (PIR) orientation for new directors and coordinators and orientation on the Head Start Program Performance Standards (historically, these have been held at least annually).

- + Development of topics and schedules of workshops provided at State/cluster sites.

- + Presentations/workshops for State and National Head Start Association conferences and national Head Start Bureau events.

- + Participation in meetings/events sponsored by public and private organizations offering opportunities to provide T/TA-related information to appropriate constituencies.

- + Use of current technologies/approaches, such as distance learning, interactive systems computers, videos, satellite down links, internet, etc., for maximizing the dissemination and provision of T/TA.

* Training and technical assistance institutes

- + Training provided to grantees on-site, in clusters, and/or at State- or Region-wide settings, including use of the train-the-trainer model.

- + Development and implementation of opportunities for distance learning.

- + Training on newly developed Head Start materials.

- + Development and implementation of procedures for grantee staff to engage in inquiry research and in program/curriculum development opportunities.

* Information dissemination/networking

- + Regional information dissemination on T/TA to grantees and State/cluster sites.

- + Technological networks at the Regional level using innovative communication technology, particularly to disseminate information on Head Start policies and regulations.

- + Shared information and results of evaluations of consultants through the National T/TA Information Resource Bank.

- + Demonstrations of, and information on, and dissemination of materials developed by national contractors and Regional and sub-Regional HSQICs.

- + Collaboration with Head Start-sponsored or related national initiatives, such as Medicaid, immunizations, substance abuse prevention and treatment, transportation, facilities and mental health.

- + Information and/or training about Head Start Bureau publications, such as training guides.

- + Assistance in developing Head Start Family Information System (HSFIS) reports for local use, maintaining contact with the HSFIS contractor regarding the usage of the system.

- + Working with HSFIS sites, encouraging the use of the HSFIS by Head Start programs in the Region or sub-Region through the distribution of reports and other information; assisting programs in determining hardware requirements, staffing requirements, and data entry methods; maintaining contact with the Head Start mentor programs; assisting mentor programs in arranging for cluster training involving one or more mentor groups; assisting at cluster training events; maintaining contact with the HSFIS contractor regarding the performance of the

software and other aspects of ongoing usage of the system; and recommending improvements in the system.

- + Maintaining and publishing information on statewide T/TA resources including Child Care Resource and Referral programs.

- + Maintaining a video/materials resource library.

- + Contributing articles to the Head Start Bulletin.

- + Maintaining of up-to-date fact sheets on grantees and program model descriptions.

- + Maintaining a Regional or sub-Regional calendar of T/TA events.

- + Participating in semiannual national T/TA network meetings, along with quarterly meetings/conference calls with the Federal Project Officer (FPO) and the Regional HSQIC liaison.

- HSQICs should organize and structure T/TA activities to achieve maximum coordination, efficiency and effectiveness. Suggested approaches include:

- * A Regional or sub-Regional Coordinating Council comprised of various stakeholders, such as ACF Regional Office staff, the Federal Project Officer from the Head Start Bureau, State Collaboration Project grantees, State Head Start Association representatives and other T/TA providers in the areas of child care, early childhood education, health, family development, community development and program planning. The Council would support the HSQIC in identifying needs for T/TA, developing a Regional or sub-Regional T/TA plan, connecting and coordinating services in and among the different levels of the system and to reach out to the community. It would meet regularly to consult with the leadership of the HSQIC in assessing needs, developing a fair balance for the provision of services among grantees, and preparing and updating Regional or sub-Regional T/TA plans.

- * State-/cluster-based activities functioning as extensions of the HSQIC to provide joint training opportunities to clusters of grantees that have the same needs based on needs assessments. The use of expert trainers and consultants to provide T/TA to grantees within the cluster and to interact with American Indian, Migrant and State Head Start Associations, State agencies and community organizations to coordinate services and to track relevant State legislation and regulations. Work with "exemplary" grantees to help them move forward as the new system is designed. Trainers need a knowledge base and an awareness of adult continuous learning and applicability to issues in the community/program to be served. Large States may have more than one cluster site and smaller States may share clusters of grantees. The American Indian Programs Branch grantees may have up to three cluster sites and the Migrant Programs Branch grantees may have up to two cluster sites. State/cluster site staff could be co-located with other T/TA providers.

- * Regular meetings, communications:

- + Use of technology, such as satellites, computers, voice links, internet, etc.

- + Use of interconnected feedback loops for the purpose of issue identification, policy interpretations, evaluation, etc.

- * Collaboration with Community-Based Child Care:

- + Assistance in creating and managing partnership strategies with child care and early childhood agencies and providers to meet the needs of working families and parent preparing for employment.

- + Assistance to Head Start grantees in managing multiple sources of funding to support high quality, full-day/full-year services.

- + Assistance in adapting staffing patterns, classroom- and home-based child development services and family involvement and support.

- + Assistance to State Head Start Associations, State Collaboration Projects, state and community early childhood agencies and Head Start grantees in systematic approaches to needs, assessment, planning, funding, and staff development in early care and education services.

- * Linkages with Federal-State and other partners, such as the U.S. Departments of Agriculture, Labor, Housing and Urban Development, Transportation, Education, federally recognized Tribes, and institutions of higher learning.

- Geographic Coverage

- * Types of grantees in service area: Large/small, rural/urban, center-based, home-based, Early Head Start, full-day, part-day.

- * Level of quality among grantees:

- + Assistance to well performing grantees in developing their own T/TA services.

- + Identification of grantees to serve as mentors to new and/or deficient and seriously deficient grantees. Assistance in the management of supplementary grant funds for the mentoring grantees and collection of evaluative information on the mentoring efforts.

- + Assistance in designing T/TA plans for deficient and seriously deficient grantees, at their request and in collaboration with the ACF Regional Office, American Indian Programs and Migrant Programs Branches to enable them to meet the Head Start Program Performance Standards.

- Management and staffing issues (including consultant banks)

- + Sufficient HSQC staff to coordinate training, manage staff and consultant resources, provide necessary subject-specific expertise, and administer cooperative agreement fiscal resources.

- * Sufficient leadership and consultant expertise to address health responsibilities, including the specialty areas (medical, dental, nutrition, mental health) at the Regional or sub-Regional and State/cluster sites.

- * Family and Community Partnership/Governance:

- + Skilled leadership in establishing linkages and effective interactions with Federal and State partners, distributing resource materials and conducting regular ongoing State/cluster Policy Council training with an emphasis on the timely training of parents who are new Policy Council members, arranging for follow-up on-site and being fully knowledgeable of each State's unique approach to Welfare Reform and providing on-site consultation regarding issues or effects which may impact Head Start programs and their operations/services.

- * Management and Leadership

- + Sufficient staff and consultant support for ensuring training and technical assistance opportunities in management, human resources and leadership in addressing the Head Start Program Performance Standards.

- * Child Care Responsibilities

- + Skilled leadership and support on assessing needs for training and technical assistance on Head Start/Child Care partnership issues.

- + Assistance in locating and describing innovative and successful Head Start/Child Care partnerships which expand the availability of high quality full-day/full-year services.

- + Assistance in State and Regional networking strategies for exchange of strategies and problem-solving around the challenges of partnership approaches to funding and managing high quality full-day/full-year services by Head Start grantees and other community-based child care and early childhood agencies.

- + Collaboration with other Federal, State, and local child care and early childhood agencies, programs and professional organizations in training, technical assistance, professional development, and planning efforts.

- * HSFCIS expertise to encourage its use by Head Start programs in each service area.

- + Assisting programs in determining hardware requirements, grantee staffing requirements, data entry methods, etc.

- + Maintaining contact with the mentor programs through e-mail, conference calls, etc., in order to assist mentor programs in arranging for cluster training.

- * Transportation expertise:

- + Maintaining a resource library of transportation materials, including such topics as vehicles, driver training, monitor training, child restraints, model transportation plans, State pupil transportation safety plans, etc.

- + Assisting programs in keeping abreast of various Regional or sub-Regional and national conferences sponsored by school transportation organizations and legislative activities at the State and Regional level.

- + Familiarity with the driver training requirements for each State in the Regional or sub-Regional service area; assisting programs in accessing driver training needs and acquiring training resources, including train-the-trainer programs.

- + Development of classroom materials and other guidance materials for use in educating children and parents about safe riding practices and safe pedestrian practices.

- + Assisting programs in determining the transportation option most suitable for their program, e.g., coordinated systems, other contract arrangements, fleet purchases.

- * Facilities expertise:

- + Provide training for grantees and ACF staff in conducting cost analysis when applying for funding for renovation, construction or purchase of facilities.

- * Child development expertise to help grantees provide quality services for pregnant women, infant/toddlers, and children to age five.

- * Consultant Pool

- + A Regional or sub-Regional consultant pool, identified, screened, contracted and

linked to the National T/TA Information Resource Bank.

- + Provision of orientation and ongoing training for consultants.

- + Management of on-site activities of consultants at the Regional, sub-Regional or State/cluster site.

- + Monitoring and evaluation of Regional-level T/TA and the performance of consultants through on-site observations, interviews with grantee staff, reviews of workshop evaluations, etc.

- + Maintenance of evaluation data on consultants for the use of national network.

- + Sufficient staff at State/cluster sites to broker/coordinate local resources, strengthen training and staff development, assess the needs of individual grantees and assist with the development of grantee T/TA plans.

Appendix C—OMB State Single Point of Contact Listing

Arizona

Joni Saad, Arizona State Clearinghouse, 3800 N. Central Avenue, Fourteenth Floor, Phoenix, Arizona 85012, Telephone (602) 280-1315, FAX: (602) 280-8144.

Arkansas

Mr. Tracy L. Copelend, Manager, State Clearinghouse, Office of Intergovernmental Services, Department of Finance and Administration, 1515 W. 7th St., Room 412, Little Rock, Arkansas 72203, Telephone: (501) 682-1074, FAX: (501) 682-5206.

California

Grants Coordinator, Office of Planning & Research, 1400 Tenth Street, Room 121, Sacramento, California 95814, Telephone (916) 323-7480, FAX (916) 323-3018.

Delaware

Francine Booth, State Single Point of Contact Executive Department, Thomas Collins Building, P.O. box 1401, Dover, Delaware 19903, Telephone: (202) 739-3326, FAX (302) 739-5661.

District of Columbia

Charles Nichols, State Single Point of Contact, Office of Grants Mgmt. & Dev., 717 14th Street, N.W.—Suite 500, Washington, D.C. 20005, Telephone: (202) 727-6554, FAX (202) 727-1617.

Florida

Florida State Clearinghouse, Department of Community Affairs, 2740 Centerview Drive, Tallahassee, Florida 32399-2100, Telephone: (904) 922-5438, FAX (904) 487-2899.

Georgia

Tom L. Reid, III, Administrator, Georgia State Clearinghouse, 254 Washington Street, S.W.—Room 401J, Atlanta, Georgia 30334, Telephone: (404) 656-3855 or (404) 656-3829, FAX (404) 656-7938.

Illinois

Virginia Bova, State Single Point of Contact, Department of Commerce and Community Affairs, James R. Thompson Center, 100 West Randolph, Suite 3-400, Chicago, Illinois 60601, Telephone: (312) 814-6028, FAX (312) 814-1800.

Indiana

Amy Brewer, State Budget Agency, 212 State House, Indianapolis, Indiana

- 46204, Telephone: (317) 232-5619, FAX (317) 233-3323.
- Iowa**
Steven R. McCann, Division for Community Assistance, Iowa Department of Economic Development, 200 East Grand Avenue, Des Moines, Iowa 50309, Telephone: (515) 242-4719, FAX (515) 242-4859.
- Kentucky**
Ronald W. Cook, Office of the Governor, Department of Local Government, 1024 Capitol Center Drive, Frankfort, Kentucky 40601-8204, Telephone: (502) 573-2382, FAX: (502) 573-2512.
- Maine**
Joyce Benson, State Planning Office, State House Station #38, Augusta, Maine 04333, Telephone: (207) 287-3261, FAX: (207) 287-6489.
- Maryland**
William G. Carroll, Manager, State Clearinghouse for Intergovernmental Assistance, Maryland Office of Planning, 301 W. Preston Street—Room 1104, Baltimore, Maryland 21201-2365, Staff Contact: Linda Janey, Telephone: (410) 225-4490, FAX: (410) 225-4480.
- Michigan**
Richard Pfaff, Southeast Michigan Council of Governments, 1900 Edison Plaza, 660 Plaza Drive, Detroit, Michigan 48226, Telephone: (313) 961-4266, FAX: (313) 961-4869.
- Mississippi**
Cathy Malette, Clearinghouse Officer, Department of Finance and Administration, 455 North Lamar Street, Jackson, Mississippi 39202-3087, Telephone: (601) 359-6762, FAX: (601) 359-6764.
- Missouri**
Lois Pohl, Federal Assistance Clearinghouse, Office of Administration, P.O. Box 809, Room 760, Truman Building, Jefferson City, Missouri 65102, Telephone: (314) 751-4834, FAX: (314) 751-7819.
- Nevada**
Department of Administration, State Clearinghouse, Capitol Complex, Carson City, Nevada 89710, Telephone: (702) 687-4065, FAX: (702) 687-3983.
- New Hampshire**
Jeffrey H. Taylor, Director, New Hampshire Office of State Planning, Attn: Intergovernmental Review Process, Mike Blake, 2½ Beacon Street, Concord, New Hampshire 03301, Telephone: (603) 271-2155, FAX: (603) 271-1728.
- New Mexico**
Robert Peters, State Budget Division, Room 190 Bataan Memorial Building, Santa Fe, New Mexico 87503, Telephone: (505) 827-3640.
- New York**
New York State Clearinghouse, Division of the Budget, State Capitol, Albany, New York 12224, Telephone: (518) 474-1605.
- North Carolina**
Chrys Baggett, Director, N.C. State Clearinghouse, Office of the Secretary of Admin., 116 West Jones Street, Raleigh, North Carolina 27603-8003, Telephone: (919) 733-7232, FAX: (919) 733-9571.
- North Dakota**
North Dakota Single Point of Contact, Office of Intergovernmental Assistance, 600 East Boulevard Avenue, Bismarck, North Dakota 58505-0170, Telephone: (701) 224-2094, FAX: (701) 224-2308.
- Ohio**
Larry Weaver, State Single Point of Contact, State Clearinghouse, Office of Budget and Management, 30 East Broad Street, 34th Floor, Columbus, Ohio 43266-0411.
Please direct correspondence and questions about intergovernmental review to: Linda Wise, Telephone: (614) 466-0698, FAX: (614) 466-5400.
- Rhode Island**
Daniel W. Varin, Associate Director, Department of Administration/Division of Planning, One Capitol Hill, 4th Floor, Providence, Rhode Island 02908-5870, Telephone: (401) 277-2656, FAX: (401) 277-2083.
Please direct correspondence and questions to: Review Coordinator, Office of Strategic Planning.
- South Carolina**
Omeagia Burgess, State Single Point of Contact, Grant Services, Office of the Governor, 1205 Pendleton Street—Room 477, Columbia, South Carolina 29201, Telephone: (803) 734-0494, FAX: (803) 734-0385.
- Texas**
Tom Adams, Governors Office, Director, Intergovernmental Coordination, P.O. Box 12428, Austin, Texas 78711, Telephone: (512) 463-1771, FAX: (512) 463-1888.
- Utah**
Carolyn Wright, Utah State Clearinghouse, Office of Planning and Budget, Room 116, State Capitol, Salt Lake City, Utah 84114, Telephone: (801) 538-1535, FAX: (801) 538-1547.
- West Virginia**
Fred Cutlip, Director, Community Development Division, W. Virginia Development Office, Building #6, Room 553, Charleston, West Virginia 25305, Telephone: (304) 558-4010, FAX: (304) 558-3248.
- Wisconsin**
Martha Kerner, Section Chief, State/Federal Regulations, Wisconsin Department of Administration, 101 East Wilson Street—6th Floor, P.O. Box 7868, Madison, Wisconsin 53707, Telephone: (608) 266-2125, FAX: (608) 267-6931.
- Wyoming**
Sheryl Jeffries, State Single Point of Contact, Office of the Governor, State Capital, Room 124, Cheyenne, Wyoming 82002, Telephone: (307) 777-5930, FAX: (307) 632-3909.
- Territories**
- Guam**
Mr. Giovanni T. Sgambelluri, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910, Telephone: 011-671-472-2285, FAX: 011-671-472-2825.
- Puerto Rico**
Norma Burgos/Jose E. Caro, Chairwoman/Director, Puerto Rico Planning Board, Federal Proposals Review Office, Minillas Government Center, P.O. 41119, San Juan, Puerto Rico 00940-1119, Telephone: (809) 727-4444, (809) 723-6190, FAX: (809) 724-3270, (809) 724-3103.
- North Mariana Islands**
Mr. Alvaro A. Santos, Executive Officer, State Single Point of Contract, Office of Management and Budget, Office of the Governor, Saipan, MP, Telephone: (670) 664-2256, FAX: (670) 664-2272.
Contact Person: Ms. Jacoba T. Seman, Federal Programs Coordinator, Telephone: (670) 644-2289, FAX: (670) 644-2272.
- Virgin Islands**
Jose George, Director, Office of Management and Budget, #41 Norregade Emancipation Garden Station, Second Floor, Saint Thomas, Virgin Islands 00802.
Please direct all questions and correspondence about intergovernmental review to: Linda Clarke, Telephone: (809) 774-0750, FAX: (809) 776-0069.
- BILLING CODE 4184-01-P**

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE		2. DATE SUBMITTED	Applicant Identifier
1. TYPE OF SUBMISSION: <i>Application</i> <input type="checkbox"/> Construction	<i>Preapplication</i> <input type="checkbox"/> Construction	3. DATE RECEIVED BY STATE	State Application Identifier
<input type="checkbox"/> Non-Construction	<input type="checkbox"/> Non-Construction	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier
5. APPLICANT INFORMATION			
Legal Name:		Organizational Unit:	
Address (give city, county, state, and zip code):		Name and telephone number of the person to be contacted on matters involving this application (give area code)	
6. EMPLOYER IDENTIFICATION NUMBER (EIN): <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>		7. TYPE OF APPLICANT: (enter appropriate letter in box) 	
8. TYPE OF APPLICATION: <input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision		A. State B. County C. Municipal D. Township E. Interstate F. Intermunicipal G. Special District	
If Revision, enter appropriate letter(s) in box(es): A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration Other (specify): _____		H. Independent School Dist. I. State Controlled Institution of Higher Learning J. Private University K. Indian Tribe L. Individual M. Profit Organization N. Other (Specify) _____	
9. NAME OF FEDERAL AGENCY:		11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:	
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>		12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):	
13. PROPOSED PROJECT: Start Date Ending Date		14. CONGRESSIONAL DISTRICTS OF: a. Applicant b. Project	
15. ESTIMATED FUNDING:		16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?	
a. Federal	\$.00	a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: _____ DATE _____	
b. Applicant	\$.00	b. NO. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372	
c. State	\$.00	<input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	
d. Local	\$.00	17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?	
e. Other	\$.00	<input type="checkbox"/> Yes If "Yes," attach an explanation. <input type="checkbox"/> No	
f. Program Income	\$.00	18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED	
g. TOTAL	\$.00	a. Typed Name of Authorized Representative b. Title c. Telephone number	
d. Signature of Authorized Representative		e. Date Signed	

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
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Instructions for the SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item and Entry

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
 - “New” means a new assistance award.
 - “Continuation” means an extension for an additional funding/budget period for a project with a projected completion date.
 - “Revision” means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclosed the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contract (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BILLING CODE 4184-01-P

OMB Approval No. 0348-0044

BUDGET INFORMATION — Non-Construction Programs

SECTION A — BUDGET SUMMARY						
Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		\$	\$	\$	\$	\$
2.						
3.						
4.						
5. TOTALS		\$	\$	\$	\$	\$

SECTION B — BUDGET CATEGORIES					
Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1)	(2)	(3)	(4)	
a. Personnel	\$	\$	\$	\$	\$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges (sum of 6a - 6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	\$	\$	\$	\$	\$
7. Program Income	\$	\$	\$	\$	\$

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SECTION C - NON-FEDERAL RESOURCES					
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS	
8.	\$	\$	\$	\$	
9.					
10.					
11.					
12. TOTALS (sum of lines 8 and 11)	\$	\$	\$	\$	
SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	FUTURE FUNDING PERIODS (Years)			
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	\$	\$	\$	\$	\$
14. NonFederal					
15. TOTAL (sum of lines 13 and 14)	\$	\$	\$	\$	\$
SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT					
(a) Grant Program	FUTURE FUNDING PERIODS (Years)				
	(b) First	(c) Second	(d) Third	(e) Fourth	
16.	\$	\$	\$	\$	
17.					
18.					
19.					
20. TOTALS (sum of lines 16 - 19)	\$	\$	\$	\$	
SECTION F - OTHER BUDGET INFORMATION (Attach additional Sheets if Necessary)					
21. Direct Charges:		22. Indirect Charges:			
23. Remarks					

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Instructions for the SF-424A*General Instructions*

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a–k of Section B.

Section A. Budget Summary Lines 1–4, Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in Column (a) and the respective catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1–4, Columns (c) through (g.)

For new applications, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the

estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5—Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1–4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a–i—Show the totals of Lines 6a to 6h in each column.

Line 6j—Show the amount of indirect cost.

Line 6k—Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)–(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7—Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal-Resources

Lines 8–11—Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a)—Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b)—Enter the contribution to be made by the applicant.

Column (c)—Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d)—Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e)—Enter totals of Columns (b), (c), and (d).

Line 12—Enter the total for each of Column (b)–(e). The amount in Column (e) should be equal to the amount of Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13—Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14—Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15—Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16–19—Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20—Enter the total for each of the Columns (b)–(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21—Use this space to explain amounts for individual direct object-class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22—Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23—Provide any other explanations or comments deemed necessary.

OMB Approval No. 0348-0040

ASSURANCES — NON-CONSTRUCTION PROGRAMS

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. § 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

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10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is \$10,000 or more.
11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).
12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.
13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).
14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.
15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.
16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.
17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.
18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE	
APPLICANT ORGANIZATION		DATE SUBMITTED

U.S. Department of Health and Human Services
Certification Regarding Drug-Free Workplace Requirements
Grantees Other Than Individuals

By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

This certification is required by regulations implementing the Drug-Free Workplace Act of 1988, 45 CFR Part 76, Subpart F. The regulations, published in the May 25, 1990 Federal Register, require certification by grantees that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the Department of Health and Human Services (HHS) determines to award the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, HHS, in addition to any other remedies available to the Federal Government, may taken action authorized under the Drug-Free Workplace Act. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment.

Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios.)

If the workplace identified to HHS changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see above).

Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

"Controlled substance" means a controlled substance in Schedules I through V of the Controlled Substances Act (21 USC 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15).

"Conviction" means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

"Criminal drug statute" means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

"Employee" means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about:

(1) The dangers of drug abuse in the workplace; (2) The grantee's policy of maintaining a drug-free workplace; (3) Any available drug counseling, rehabilitation, and employee assistance programs; and, (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and, (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or, (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant (use attachments, if needed):

Place of Performance (Street address, City, County, State, ZIP Code) _____

Check ☐ if there are workplaces on file that are not identified here.

Sections 76.630(c) and (d)(2) and 76.635(a)(1) and (b) provide that a Federal agency may designate a central receipt point for STATE-WIDE AND STATE AGENCY-WIDE certifications, and for notification of criminal drug convictions. For the Department of Health and Human Services, the central receipt point is: Division of Grants Management and Oversight, Office of Management and Acquisition, Department of Health and Human Services, Room 517-D, 200 Independence Avenue, S.W., Washington, D.C. 20201.

DGMO Form#2 Revised May 1990

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions*Instructions for Certification*

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or had become erroneous by reason of changed circumstances.

4. The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntarily excluded, as used in this clause, have the meaning set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, [[Page 33043]] should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transaction," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions*Instructions for Certification*

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

4. The prospective primary participant shall provide immediate written notice to the department or agency to which this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

5. The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntarily excluded, as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.

6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transaction," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other

remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements or receiving stolen property;

(c) Are not presently indicated for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance

was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31 U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

State for Loan Guarantee and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL "Disclosure Form to Report Lobbying," in accordance with its instructions.

Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Signature

Title

Organization

Date

BILLING CODE 4184-01-P

DISCLOSURE OF LOBBYING ACTIVITIESApproved by OMB
0348-0046Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action: <input type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement <input type="checkbox"/> d. loan <input type="checkbox"/> e. loan guarantee <input type="checkbox"/> f. loan insurance	2. Status of Federal Action: <input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	3. Report Type: <input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change For Material Change Only: year _____ quarter _____ date of last report _____
4. Name and Address of Reporting Entity: <input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, if known: Congressional District, if known: _____	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime: Congressional District, if known: _____	
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, if applicable: _____	
8. Federal Action Number, if known:	9. Award Amount, if known: \$ _____	
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): <div style="border: 1px solid black; height: 100px; width: 100%;"></div>		
b. Individuals Performing Services (including address if different from No. 10a) (last name, first name, MI): <div style="border: 1px solid black; height: 100px; width: 100%;"></div>		
<i>(attach Continuation Sheet(s) SF-LLL-A, if necessary)</i>		
11. Amount of Payment (check all that apply): \$ _____ <input type="checkbox"/> actual <input type="checkbox"/> planned	13. Type of Payment (check all that apply): <input type="checkbox"/> a. retainer <input type="checkbox"/> b. one-time fee <input type="checkbox"/> c. commission <input type="checkbox"/> d. contingent fee <input type="checkbox"/> e. deferred <input type="checkbox"/> f. other; specify: _____	
12. Form of Payment (check all that apply): <input type="checkbox"/> a. cash <input type="checkbox"/> b. in-kind; specify: nature _____ value _____		
14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11: <div style="border: 1px solid black; height: 100px; width: 100%;"></div>		
<i>(attach Continuation Sheet(s) SF-LLL-A, if necessary)</i>		
15. Continuation Sheet(s) SF-LLL-A attached: <input type="checkbox"/> Yes <input type="checkbox"/> No		
16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____	
Federal Use Only:		Authorized for Local Reproduction Standard Form - LLL

Certification Regarding Environmental Tobacco Smoke

Public Law 103-227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1,000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

[FR Doc. 97-8840 Filed 4-7-97; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Grassroots Consumer Participation: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a grassroots consumer exchange meeting between the general public and FDA officials. The meeting will be chaired by FDA's Cincinnati District Director and is intended to encourage dialogue between consumers and FDA officials, to solicit consumers' concerns about the drug review process, drug clinical trials (including inclusion of women in clinical trials), and to discuss how FDA can improve consumer services.

DATES: The public meeting will be held on Tuesday, April 29, 1997, 9 a.m. to 12 m.

ADDRESSES: The public meeting will be held at the Cincinnati Bell Long Distance Bldg., 36 East 7th St., rm. 1703, Cincinnati, OH.

FOR FURTHER INFORMATION CONTACT: Marilyn R. Zipkes, Food and Drug Administration, 1141 Central Pkwy.,

Cincinnati, OH 45212, 513-684-3501, ext. 110.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to encourage dialogue between consumers and FDA officials, to identify consumers' current and future health concerns, and to enhance relations between consumers and FDA. There is no registration fee for this meeting. Interested persons are encouraged to register early because space is limited. To register contact the contact person listed above.

Dated: March 31, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 97-8908 Filed 4-7-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0126]

CIBA Vision Corp.; Premarket Approval of Unizyme Enzymatic Cleaner

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CIBA Vision Corp., Duluth, GA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Unizyme Enzymatic Cleaner. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 31, 1997, of the approval of the application.

DATES: Petitions for administrative review by May 8, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On August 15, 1996, CIBA Vision Corp., Duluth, GA, 30155-1518, submitted to CDRH an application for premarket approval of Unizyme Enzymatic Cleaner. The device

is a periodic cleaner and is indicated for use with (hydrogen peroxide), lens care systems in the weekly cleaning of soft (hydrophilic) contact lenses (including daily wear, extended wear, tinted lenses, and lenses prescribed for scheduled replacement).

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On January 31, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.