

Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 10, 1995.

A. Federal Reserve Bank of Atlanta
(Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Investment Bancshares Corporation*, New York, New York; to engage *de novo* through its subsidiary, *Investment Bancshares Corporation*, New York, New York, in making, acquiring, participating in and/or servicing loans secured by mortgages on real estate for Applicant's account or the account of others, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

B. Federal Reserve Bank of Chicago
(James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *First Business Bancshares, Inc.*, Madison, Wisconsin; to engage *de novo* through its subsidiary, *First Madison Capital Corp.*, Madison, Wisconsin, in commercial finance lending, pursuant to § 225.25(b)(1)(iv) of the Board's Regulation Y; and leasing of personal property, pursuant to § 225.25(b)(5) of The Board's Regulation Y. The proposed activity will be conducted throughout the state of Wisconsin.

2. *GNB Bancorporation*, Grundy Center, Iowa; to engage *de novo* through

its subsidiary, *GNB Financial Co.*, Grundy Center, Iowa, in leasing activities, pursuant to § 225.25(b)(5) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, June 20, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-15519 Filed 6-23-95; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following case:

Farooq A. Siddiqui, Ph.D., Roswell Park Cancer Institute: The Division of Research Investigations (DRI) of the Office of Research Integrity (ORI) completed an investigation into possible scientific misconduct on the part of Dr. Siddiqui while he was an employee of Roswell Park Memorial Institute. ORI finds that Dr. Siddiqui committed scientific misconduct by misrepresenting data in a published article. The research was supported by a grant award from the National Cancer Institute, National Institutes of Health, Public Health Service (PHS).

Dr. Siddiqui agreed not to appeal the misconduct finding as part of a Voluntary Settlement Agreement under which, for a period of two years, he will not apply as a principal or coprincipal investigator in any nonprocurement transactions (grants and cooperative agreements) or as a principal or coprincipal in any contract or subcontract with the United States Government. Dr. Siddiqui also is prohibited from serving on any Public Health Service advisory committee, board, and/or peer review committee for a period of two years. Also, for a two-year period the institution where he is employed will supervise his performance of work on any covered transaction including a periodic review of primary data, and certify the accuracy of any such data used in any United States Government Public Health Service grant application, contract proposal, or which is otherwise publicly reported. He has agreed to submit a letter to the journal *Biochemica et Biophysica Acta* (BBA) to retract the article entitled "Purification and

Immunological Characterization of DNA Polymerase-alpha from Human Acute Lymphoblastic Leukemia Cells" (BBA, 745:154-161, 1983).

FOR FURTHER INFORMATION, CONTACT:

Director, Division of Research Investigations, Office of Research Integrity, 301-443-5330.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95-15475 Filed 6-23-95; 8:45 am]

BILLING CODE 4160-17-P

Administration for Children and Families

Changing the Culture of Welfare Demonstration

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Announcement of the availability of funds and request for applications to create and test various cultural change models for adoption by welfare offices throughout the nation.

SUMMARY: The Administration for Children and Families (ACF) announces the availability of Federal funding to participate in intensive joint planning and development activities that would reinforce the concept of the temporary nature of welfare, and promote self-sufficiency and employment. Funding under this announcement is authorized by section 1110 of the Social Security Act governing Social Services Research and Demonstration activities.

DATES: The closing date for submission of applications is August 25, 1995.

ADDRESSES: Application receipt point: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, S.W., 6th Floor, Mailstop 6C-462 Washington, DC 20447, William McCarron, Grants Officer.

Hand delivered applications are accepted during the normal working hours of 8:00 a.m. to 4:30 p.m., Monday through Friday, on or prior to the established closing date at:

Administration for Children and Families, Division of Discretionary Grants, 6th Floor, ACF Guard Station, 901 D Street S.W., Washington DC 20447.

FOR FURTHER INFORMATION CONTACT:

Yvonne C. Howard, Project Officer, Administration for Children and Families, Office of Family Assistance, 370 L'Enfant Promenade, S.W., 5th Floor, Washington, DC 20447. Telephone (202) 401-4619.

SUPPLEMENTARY INFORMATION: The Administration for Children and Families (ACF) announces that competing applications are being accepted for Federal financial assistance to participate in intensive joint planning and development activities that would reinforce the concept of the temporary nature of welfare, and promote self-sufficiency and employment. An initial financial award for 12 months, for up to 8 sites will be made under this announcement. The Department will fund up to four (4) grantees who will be selected on a competitive basis to receive second year continuation grants for implementation of cultural change models. The recipients will be expected to enter into a cooperative agreement with ACF.

This program announcement consists of four parts. Part I provides background information about the Changing the Culture of Welfare (CCW) demonstration. Part II describes the activities supported by this announcement and application requirements. Part III describes the application review process. Part IV provides information and instructions for the development and submission of applications. The forms to be used for submitting an application follow Part IV.

Part I—Introduction

Current welfare reform proposals emphasize work, responsibility and the temporary nature of welfare. The focus of the Aid to Families with Dependent Children (AFDC) program is changing from providing benefits to preventing welfare dependency. There is growing consensus that AFDC benefits should be transitional, time-limited assistance, requiring a goal-oriented partnership between the welfare agency and the AFDC client. Such a partnership should be designed to help the client recognize the value of work and construct a plan to enter the job market and/or training to quickly achieve economic self-sufficiency.

Welfare reform initiatives in the 1980s and 1990s exemplify States' efforts to seek alternative methods of reducing welfare dependency. Reform has primarily been sought through waivers of statutory provisions, seen as barriers to achieving economic independence. In the welfare debate, another emerging issue has been the need for a radical culture change in the welfare system and the methods of assistance provided to the AFDC families.

Part II—Project Design

Purpose

The purpose of the demonstration project is to provide an opportunity for State/local IV-A agencies who: (1) want to design and implement cultural change strategies or (2) are already implementing cultural change strategies successfully but want to further expand their initiatives, to focus more strongly on work, and make the system more supportive of self-sufficiency efforts.

State and local welfare agencies are on the front line of the needed culture change since change must begin where the client meets the worker. In focusing on what the client needs to become self-sufficient, workers, supervisors, and administrators must view their jobs in a broader context. Workers must be empowered to participate in changing the culture of the welfare office and helping clients move from dependence to independence.

This culture change may be achieved by a variety of different approaches, including changes in management style, staff training, performance measurement and changes to the AFDC and JOBS rules which are perceived to impede the transition from welfare dependency to economic self-sufficiency.

Sites will need to create and test cultural change models and look at the impacts, costs, and benefits of their models. They will need to demonstrate how the model can be expanded and provide up-front delivery of services to promote employment opportunities and portray welfare as a transitional program.

They will need to also demonstrate how the job of the AFDC worker has changed, or will change, from one of determining eligibility and payment accuracy to one of financial consultant/customer service agent. This role includes working with the client to explore options and alternatives to public assistance, resources available in the community to meet immediate client needs, demonstrating the financial benefits of employment vs. receipt of welfare, and marketing (employment opportunities to the client, and clients to potential employers) etc.

Eligible Applicants

Financial assistance under this announcement is limited to State and local IV-A agencies. An application from a local IV-A agency must be approved by the State IV-A agency.

ACF is interested in providing financial support to IV-A agencies with experience in, or a demonstrated commitment to changing the culture of

welfare. Examples of cultural change include:

1. Training management and staff, as part of a overall process redesign geared toward employment and self-sufficiency, including customer relations training.
2. Improving and modifying technology to support the line worker's ability to service clients.
3. Implementing performance standards for evaluating staff with an emphasis on job placement standards as an important criteria.
4. Establishing new criteria and incentives to reward staff participating in and promoting cultural change activities.
5. Implementing a competency-based case management system.
6. Reclassifying personnel positions to upgrade eligibility determination staff.
7. Co-locating administrative and client service delivery staff working on AFDC and JOBS. Combining income maintenance and JOBS responsibilities in one worker.
8. Implementing more intensive interventions to accommodate harder-to-serve populations which would include individuals with learning disabilities and/or developmental disabilities.
9. Establishing with educational institutions such as community colleges, training institutions and local employers, short term competency-based training programs linked to actual jobs.

Minimum Requirements for Project Design.

In order to compete successfully in response to this announcement, the applicant should develop a plan which:

- Includes an outline and discussion of current, or planned culture change activities at the proposed demonstration sites. This outline should include a description of the specific features/components and services that are involved with, or impacted by culture change activities, relevant demographics of the demonstration site, and the level of agency commitment and community collaboration.
- Describes how the applicant proposes to expand existing culture change strategies and how these strategies will involve a coordinated, integrated approach among, at minimum, AFDC/JOBS staff.
- Demonstrates how this model will increase the experiential/research information we now have of what AFDC clients need to become self-sufficient.
- Demonstrates how the model (or parts thereof) can be replicated in other localities.

- Includes methods for measuring the effects of the demonstration on AFDC/JOBS participants, e.g. increased participation, employment/earnings; reduced welfare dependency.

- Describes how a cost/benefit analysis will compare the direct and indirect costs with the financial and non-financial benefits of the program from the point of view of the participants; the government (Federal, State, and local); and the taxpayer.

- Includes the applicant's approach for providing assistance and training to State and county demonstration project staff, as needed.

- Provides information about other (State, local, community) resources the site will use to support this effort, including financial support (if any) for the demonstration, in addition to Federal funding.

- Provides for travel to Washington, DC (2 times) and one site visit to another project for up to three people.

In recognition of the scope of the initiative, the potential difficulty in successfully implementing and operationalizing agency culture change, and the significance of the initiative for public policy, ACF has determined that a close, cooperative working relationship between the ACF and the selected States will greatly further the public interest. Therefore, the awards made under this announcement will be cooperative agreements between ACF and the selected State IV-A agencies. It is anticipated that ACF will be involved in the performance of the initiative in the following manner:

- ACF, working in cooperation with the State, will review and comment on the agency's cultural change strategies to ensure that the project meets specified goals and objectives.

- ACF will conduct site visits, teleconferences, and meetings, as appropriate, to provide technical assistance.

- ACF will facilitate information sharing and discussions across sites.

The above-cited areas of involvement are illustrative of the anticipated level of Federal involvement with the selected States in the initiative. The exact activities will be detailed in the Cooperative Agreement which will be developed with each selected State.

Project Duration

The length of the project should not exceed two years (24 months). This announcement is soliciting applications for two-year projects. Awards, on a competitive basis, will be for an initial one-year budget period for the design and planning of the project. Up to eight recipients of this initial award will

compete among themselves for the four (4) continuation awards. Four awards for project implementation, beyond the one-year budget period but within the two-year project period will be entertained, subject to availability of funds, satisfactory progress of the recipient, and a determination that continued funding would be in the best interest of the Government.

Federal Share of the Project

The maximum Federal share of the Project is not to exceed \$1.8 million for the two-year project period, subject to the availability of funds. The maximum Federal share for the first year budget period will be \$400,000 divided among up to eight recipients. The maximum Federal share for the second year continuation grants will be \$1.4 million divided among four recipients.

Matching Requirement

Applicants must provide at least five (5) percent of the total cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. The non-Federal share may be met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. Therefore, a project requesting \$50,000 in Federal funds must include a match of at least \$2,632 (i.e., 5 percent of the sum of the Federal and the non-Federal cost of the project). The successful applicant's match must be met by the completion of the project period.

The recipient will be required to provide the agreed upon non-Federal share, even if it exceeds the required match stated above. Therefore, applicants should ensure that any amount proposed as matching funds is committed to the project prior to inclusion in its budget.

Anticipated Number of Projects to be Funded

Up to eight projects will be funded under this announcement.

Part III—The Review Process

A. Review Process and Funding Decisions

Timely applications from eligible applicants will be reviewed and scored competitively. Reviewers will use the evaluation criteria listed below to review and score the application.

In addition ACF may refer applications to other Federal or non-Federal funding sources when it is determined to be in the best interest of the Federal Government or the applicant. It may also solicit comments

from ACF Regional Office staff, other Federal agencies, interested foundations and national organizations. These comments along with those of the reviewers will be considered by ACF in making the funding decision.

In making a funding decision, ACF may give preference to applications which reflect experience in working with the cultural change strategies since such experience on the part of a recipient has the potential to substantially improve the development of a culture change model.

B. Evaluation Criteria

Using the evaluation criteria below, reviewers will review and score each application. Applicants should insure that they address each minimum requirement listed above.

Reviewers will determine the strengths and weaknesses of each application in terms of the appropriate evaluation criteria listed below, provide comments, and assign numerical scores. The point value following each criterion heading indicates the maximum numerical weight that each criterion may be given in the review process.

Review Criteria

(1) Knowledge of Changing the Culture of Welfare (25 points)

The applicant's proposal should demonstrate a good understanding of the project design and the tasks and objectives involved in the project. The application should provide: (a) evidence of organizational experience in changing the culture of welfare and/or (b) evidence of commitment to planning and implementing agency cultural change activities. The discussion should also reflect a clear understanding of "culture" change and the current emphasis on work and responsibility and transitional benefits.

(2) Approach and Project Design (30 points)

The application should include: (a) an outline of the project design which takes into account specific features the applicant wishes to address, the objectives, component(s) and services that will be impacted by the culture change strategies; (b) a description of how the applicant will involve agency staff (AFDC and JOBS) in the planning process, which staff (front-line worker/management etc.), and the level of staff involvement; and (c) the applicant's approach for providing assistance and training to agency staff to enable their full participation in the planning process.

(3) Public—Private Partnerships (15 points)

In order to maximize the potential resources of the community to provide options and alternatives to the public welfare system, the applicant should provide evidence of coordination and commitments by public, private, non-profit, community organizations and businesses to support changing the culture of welfare.

(4) Methodology (5 points)

The application should describe proposed methodology for measuring the effects of the planned demonstration on AFDC/JOBS participants and the extent to which the experiential/research knowledge will be increased.

(5) Staff Skills and Responsibilities (20 points)

It has been our experience that in order for demonstrations of this scope to be successful, the support and commitment of the administrators at the highest levels of the agency are necessary. Demonstrations such as this are under tight time constraints and require innovation and flexibility. For example, it may be necessary from time to time to provide exceptions to normal administrative processes or to establish expedited processes. Thus the support and commitment of senior official to accomplish the many tasks involved is critical. The application should discuss this issue and indicate the level of commitment to the demonstration which is proposed. The application should list key individuals who will work on the project along with a short description of the nature of their contribution. Summarize the background and experience of the project director and key project staff.

(6) Budget Appropriateness (5 points)

The application should demonstrate that the project's costs are reasonable in view of the anticipated results and benefits. Applicants may refer to the budget information presented in the Standard Forms 424 and 424A.

Part IV—Instructions for the Development and Submission of Applications

This part contains information and instructions for submitting applications in response to this announcement. Application forms are provided as part of this announcement along with a checklist for assembling an application package.

A. Required Notification of the State Single Point of Contact

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

All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Minnesota, Montana, Nebraska, Oklahoma, Oregon, Virginia, Pennsylvania, South Dakota, Washington, American Samoa and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs), listed at the end of this announcement. Applicants from these nineteen jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the "accommodate or explain" rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, S.W., 6th Floor, Mailstop 6C-462, Washington, D.C. 20447.

Refer to the beginning of this announcement under the heading

ADDRESSES, for hand delivered applications.

B. Deadline for Submittal of Applications

The closing date for submittal of applications under this program announcement is found at the beginning of this announcement under the heading **DATES**. Applications shall be considered as meeting the announced 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 cautioned to request 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 in 1 and 2 above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

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

C. Instructions for Preparing the Application

In order to assist applicants in completing the application, the Standard Forms 424 and 424A, required certifications, and a list of SPOCs have been included at the end of Part IV of this announcement. Please reproduce single-sided copies of these forms from the reprinted forms and type your information onto the copies.

Please prepare your application in accordance with the following instructions:

1. SF 424 Page 1, Application Cover Sheet

Please read the following instructions before completing the application cover sheet. An explanation of each item is included. Complete only the items specified.

Item 1. Type of Submission—Non-Construction.

Item 2. Date Submitted and Applicant Identifier—Date application is submitted to ACF and applicant's own internal control number, if applicable.

Item 3. Date Received By State—State use only (if applicable).

Item 4. Date Received by Federal Agency—Leave blank.

Item 5. Applicant Information.

Legal Name—Enter the legal name of applicant organization. For applications developed jointly, enter the name of the lead organization only. There must be a single applicant for each application.

Organizational Unit—Enter the name of the primary unit within the applicant organization which will actually carry out the project activity. If this is the same as the applicant organization, leave the organizational unit blank.

Address—Enter the complete address that the organization actually uses to receive mail, since this is the address to which all correspondence will be sent. Do not include both street address and P.O. box number unless both must be used in mailing.

Name and telephone number of the person to be contacted on matters involving this application (give area code)—Enter the full name and telephone number of a person who can respond to questions about the application. This person should be accessible at the address given.

Item 6. Employer Identification Number (EIN)—Enter the employer identification number of the applicant organization, as assigned by the Internal Revenue Service, including, if known, the Central Registry System suffix.

Item 7. Type of Applicant—Self-explanatory.

Item 8. Type of Application—New.

Item 9. Name of Federal Agency—DHHS/ACF.

Item 10. Catalog of Federal Domestic Assistance Number—93.647.

Item 11. Descriptive Title of Applicant's Project—Changing the Culture of Welfare.

Item 12. Areas Affected by Project—Leave Blank.

Item 13. Proposed Project—Enter the desired start date for the project and projected completion date. The project period must begin no later than September 30, 1995.

Item 14. Congressional District of Applicant/Project—Enter the number of the Congressional district where the applicant's principal office is located.

Items 15. Estimated Funding Levels—In completing 15a through 15f, the dollar amounts entered should reflect the total amount requested for the first 12-month budget period.

Item 15a. Enter the amount of Federal funds requested in accordance with the preceding paragraph. This amount should be no greater than the maximum amount available under this announcement for the first 12-month budget period.

Items 15b–e. Enter the amount(s) of funds from non-Federal sources that will be contributed to the proposed

project. Items b–e are considered cost-sharing or matching funds.

Item 15f. Enter the estimated amount of income, if any, expected to be generated from the proposed project. Do not add or subtract this amount from the total project amount entered under item 15g. Describe the nature, source and anticipated use of this income in the Project Narrative Statement.

Item 15g. Enter the sum of items 15a–15e.

Item 16a. Is Application Subject to Review By State Executive Order 12372 Process?—Check Yes if your State participates in the E.O. 12372 process. Enter the date the application was made available to the State for review. Select the appropriate SPOC from the listing provided at the end of Part IV. The review of the application is at the discretion of the SPOC.

Item 16b. Is Application Subject to Review By State Executive Order 12372 Process?—Check No if the program has not been selected by State for review.

Item 17. Is the Applicant Delinquent on any Federal Debt?—Check the appropriate box. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include audit disallowances, loans and taxes.

Item 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.—To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for signature of this application by this individual as the official representative must be on file in the applicant's office, and may be requested from the applicant.

Item 18a–c. Typed Name of Authorized Representative, Title, Telephone Number—Enter the name, title and telephone number of the authorized representative of the applicant organization.

Item 18d. Signature of Authorized Representative—Signature of the authorized representative named in Item 18a. At least one copy of the application must have an original signature. Use colored ink (not black) so that the original signature is easily identified.

Item 18e. Date Signed—Enter the date the application was signed by the authorized representative.

2. SF 424A—Budget Information—Non-Construction Programs

This is a form used by many Federal agencies. For this application, Sections A, B, C, and E are to be completed. Sections D and F do not need to be completed.

Section A—Budget Summary. Line 1: Column (a): Enter Changing the Culture of Welfare;

Column (b): Enter 93.647.

Columns (c) and (d): Leave blank.

Columns (e), (f) and (g): Enter the appropriate amounts needed to support the project for the first budget period.

Section B—Budget Categories. This budget should include the Federal as well as non-Federal funding for the proposed project for the first 12-month budget period. The budget should relate to item 15g, total funding, on the SF 424. Under column (5), enter the total requirements for funds (Federal and non-Federal) by object class category.

A separate budget justification should be included to explain fully and justify items, as indicated below. The types of information to be included in the justification are indicated under each category. The budget justification should immediately follow the second page of the SF 424A.

Personnel—Line 6a. Enter the total costs of salaries and wages of applicant/grantee staff. Do not include the costs of consultants, which should be included on line 6h, Other.

Justification: Identify the staff, if known, specify. Specify by title or name the percentage of time allocated to the project, the individual annual salaries, and the cost to the project (both Federal and non-Federal) of the organization's staff who will be working on the project.

Fringe Benefits—Line 6b. Enter the total costs of fringe benefits.

Justification: Provide a break-down of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

Travel—6c. Enter total costs of out-of-town travel (travel requiring per diem) for staff of the project. Do not enter costs for consultant's travel or local transportation, which should be included on Line 6h, Other.

Justification: Include the name(s) of traveler(s), total number of trips, destinations, length of stay, transportation costs and subsistence allowances.

Equipment—Line 6d. Enter the total costs of all equipment to be acquired by the project. For grants governed by the administrative requirements of 45 CFR part 74, equipment means an article of

nonexpendable tangible personal property having an acquisition cost of \$5000 or more per unit and a useful life of more than one year. For grants governed by the administrative requirements of 45 CFR part 92, equipment is tangible, nonexpendable personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit.

Justification: Equipment to be purchased with Federal funds must be justified. The equipment must be required to conduct the project, and the applicant organization or its subgrantees must not have the equipment or a reasonable facsimile available to the project. The justification also must contain plans for future use or disposal of the equipment after the project ends.

Supplies—Line 6e. Enter the total costs of all tangible expendable personal property (supplies) other than those included on Line 6d.

Justification: Specify general categories of supplies and their costs.

Contractual—Line 6f. Enter the total costs of all contracts, including procurement contracts (except those which belong on other lines such as equipment, supplies, etc.) and contracts with secondary recipient organizations. Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals on this line.

Justification: Attach a list of contractors, indicating the names of the organizations, the purposes of the contracts, and the estimated dollar amounts of the awards as part of the budget justification. Whenever the applicant/grantee intends to delegate part or all of the program to another agency, the applicant/grantee must complete this section (Section B, Budget Categories) for each delegate agency by agency title, along with the supporting information. The total cost of all such agencies will be part of the amount shown on Line 6f. Provide backup documentation identifying the name of contractor, purpose of contract, and major cost elements.

Construction—Line 6g. Not applicable. New construction is not allowable.

Other—Line 6h. Enter the total of all other costs. Where applicable, such costs may include, but are not limited to: insurance; medical and dental costs; noncontractual fees and travel paid directly to individual consultants; local transportation (all travel which does not require per diem is considered local travel); space and equipment rentals; printing and publication; computer use; training costs, including tuition and stipends; training service costs,

including wage payments to individuals and supportive service payments; and staff development costs. Note that costs identified as miscellaneous and honoraria are not allowable.

Justification: Specify the costs included.

Total Direct Charges—Line 6i. Enter the total of Lines 6a through 6h.

Indirect Charges—6j. Enter the total amount of indirect charges (costs). If no indirect costs are requested, enter none. Local and State governments should enter the amount of indirect costs determined in accordance with HHS requirements. When an indirect cost rate is requested, these costs are included in the indirect cost pool and should not be charged again as direct costs to the grant. In the case of training grants to other than State or local governments (as defined in title 45, Code of Federal Regulations, part 74), the Federal reimbursement of indirect costs will be limited to the lesser of the negotiated (or actual) indirect cost rate or 8 percent of the amount allowed for direct costs, exclusive of any equipment charges, rental of space, tuition and fees, post-doctoral training allowances, contractual items, and alterations and renovations.

Justification: Enclose a copy of the indirect cost rate agreement, if applicable.

Total—Line 6k. Enter the total amounts of lines 6i and 6j.

Program Income—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.

Justification: Describe the nature, source, and anticipated use of program income in the Program Narrative Statement.

Section C—Non-Federal Resources. This section summarizes the amounts of non-Federal resources that will be applied to the grant. On lines 8–11, list estimates for each projected budget period within the total project period (if an additional line is needed, use line 23 and label it appropriately). Enter total amounts on line 12.

In-kind contributions are defined in title 45 of the Code of Federal Regulations, Part 74.2., as the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefiting and specifically identifiable to the project or program.

Justification: Describe third party in-kind contributions, if included.

Section D—Forecasted Cash Needs. Not applicable.

Section E—Budget Estimate of Federal Funds Needed For Balance of the Project. On lines 16–19, list estimates for Federal assistance required for future budget periods within the total project period. List estimated total amounts on line 20.

Section F—Other Budget Information. Not applicable.

3. Program Narrative Statement

The Program Narrative Statement should be clear, concise, and address the specific requirements mentioned under Part II. The narrative should also provide information concerning how the application meets the evaluation criteria using the following headings:

- (a) *Knowledge of Changing the Culture of Welfare;*
- (b) *Approach and Project Design;*
- (c) *Public-Private Partnerships;*
- (d) *Methodology;*
- (e) *Staff Skills and Responsibilities;*
- (f) *Budget Appropriateness.*

The specific information to be included under each of these headings is described in section B of Part III—Evaluation Criteria.

The narrative should be typed double-spaced. All pages of the narrative (including charts, references, footnotes, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with Organizational Experience. The length of the application, including the application forms and all attachments, should not exceed 125 pages.

4. Assurances/Certifications

Applicants are required to file an SF 424B, Assurances—Non-Construction Programs, and the Certification Regarding Lobbying. Both must be signed and returned with the application. In addition, applicants must certify their compliance with: (1) Drug-Free Workplace Requirements; and (2) Debarment and Other Responsibilities. These certifications are self-explanatory. Copies of these assurances and certifications are reprinted at the end of this announcement and should be reproduced, as necessary. A duly authorized representative of the applicant organization must certify that the applicant is in compliance with these assurances and certifications. A signature on the SF 424 indicates compliance with Drug-Free Workplace and Debarment Notices and Public Law 103–227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994.

D. Checklist for a Complete Application

The checklist below is for your use to ensure that your application package has been properly prepared.

- One original application, signed and dated, plus two copies.
- Complete application length should not exceed 125 pages.
- A complete application consists of the following items in this order:
 - Application for Federal Assistance (SF 424);
 - A completed SPOC certification with the date of SPOC contact entered in line 16, page 1 of the SF 424 if applicable;
 - Budget Information—Non-construction programs (SF 424A);

- Budget Justification for SF 424A Section B—Budget Categories;
- Letter from the Internal Revenue Service to prove nonprofit status, if necessary;
- Copy of the applicant's approved indirect cost rate agreement, if appropriate;
- Program Narrative Statement (See Part III, Section C);
- Assurances—Non-construction programs (SF 424B); and
- Certification Regarding Lobbying.

E. Submitting the Application

Each application package must include an original and two copies of the complete application. Each copy

should be stapled securely. All pages of the narrative (including charts, tables, maps, exhibits, etc.) must be sequentially numbered. In order to facilitate handling, please do not use covers, binders, or tabs.

Applicant should include a self-addressed, stamped acknowledgment card. All applicants will be notified automatically about the receipt of their application.

Catalog of Federal Domestic Assistance 93.647.

Dated: May 22, 1995.

Lavinia Limon,

Director, Office of Family Assistance.

BILLING CODE 4184-01-P

APPLICATION FOR
FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

1. TYPE OF SUBMISSION: <i>Application</i> <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		<i>Preapplication</i> <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		2. DATE SUBMITTED	Applicant Identifier
				3. DATE RECEIVED BY STATE	State Application Identifier
				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): [][] - [][][][][][][][][][][]			7. TYPE OF APPLICANT: (enter appropriate letter in box) <input type="checkbox"/>		
8. TYPE OF APPLICATION: <input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es): <input type="checkbox"/> <input type="checkbox"/> A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration Other (specify):			A. State B. County C. Municipal D. Township E. Interstate F. Intermunicipal G. Special District 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:					
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: [][][] a [][][][][]		11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT: TITLE:			
12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):					
13. PROPOSED PROJECT:		14. CONGRESSIONAL DISTRICTS OF:			
Start Date	Ending Date	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				
e. Other	\$.00				
f. Program Income	\$.00	17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?			
g. TOTAL	\$.00	<input type="checkbox"/> Yes If "Yes," attach an explanation. <input type="checkbox"/> No			
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					
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)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

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) and 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, enclose 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 Contact (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		Total (g)
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	
1.		\$	\$	\$	\$	\$
2.						
3.						
4.						
5. TOTALS		\$	\$	\$	\$	\$

SECTION B — BUDGET CATEGORIES

Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY					Total (5)
	(1)	(2)	(3)	(4)	(5)	
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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Standard Form 424A (4-88)
Prescribed by OMB Circular A-102

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	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					

SF 424A (4-88) Page 2
Prescribed by OMB Circular A-102

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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 Columns (b)-(e). The amount in column (e)

should be equal to the amount on 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

Line 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.

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 directive.

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 (2) 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 non-discrimination 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.

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 if \$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 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

Applicant Organization

Title

Date Submitted

Executive Order 12373—State Single Points of Contact

Arizona

Mrs. Janice Dunn, ATTN: Arizona State Clearinghouse, 3800 N. Central Avenue, 14th Floor, Phoenix, Arizona 85012, Telephone (602) 280-1315

Arkansas

Tracie L. Copeland, Manager, State Clearinghouse, Office of Intergovernmental Services, Department of Finance and Administration, P.O. Box 3278, Little Rock, Arkansas 72203, Telephone (501) 682-1074

California

Glenn Stober, Grants, Coordinator, Office of Planning and Research, 1400 Tenth Street, Sacramento, California 95814, Telephone (916) 323-7480

Delaware

Ms. Francine Booth, State Single Point of Contact, Executive Department, Thomas Collins Building, Dover, Delaware 19903, Telephone (302) 736-3326

District of Columbia

Rodney T. Hallman, State Single Point of Contact, Office of Grants Management and Development, 717 14th Street, N.W., Suite 500, Washington, D.C. 20005, Telephone (202) 727-6551

Florida

Florida State Clearinghouse, Intergovernmental Affairs Policy Unit, Executive Office of the Governor, Office of Planning and Budgeting, The Capitol, Tallahassee, Florida 32399-0001, Telephone (904) 488-8441

Georgia

Mr. Charles H. Badger, Administrator, Georgia State Clearinghouse, 254 Washington Street, S.W., Atlanta, Georgia 30334, Telephone (404) 656-3855

Illinois

Steve Klokkenga, State Single Point of Contact, Office of the Governor, 107 Stratton Building, Springfield, Illinois 62706, Telephone (217) 782-1671

Indiana

Jean S. Blackwell, Budget Director, State Budget Agency, 212 State House, Indianapolis, Indiana 46204, Telephone (317) 232-5610

Iowa

Mr. Steven R. McCann, Division of Community Progress, Iowa Department of Economic Development, 200 East Grand Avenue, Des Moines, Iowa 50309, Telephone (515) 281-3725

Kentucky

Ronald W. Cook, Office of the Governor,
Department of Local Government, 1024
Capitol Center Drive, Frankfort, Kentucky
40601, Telephone (502) 564-2382

Maine

Ms. Joyce Benson, State Planning Office,
State House Station #38, Augusta, Maine
04333, Telephone (207) 289-3261

Maryland

Ms. Mary Abrams, Chief, Maryland State
Clearinghouse, Department of State
Planning, 301 West Preston Street,
Baltimore, Maryland 21201-2365,
Telephone (301) 225-4490

Massachusetts

Karen Arone, State Clearinghouse, Executive
Office of Communities and Development,
100 Cambridge Street, Room 1803, Boston,
Massachusetts 02202, Telephone (617)
727-7001

Michigan

Richard S. Pastula, Director, Michigan
Department of Commerce, Lansing,
Michigan 48909, Telephone (517) 373-
7356

Mississippi

Ms. Cathy Mallette, Clearinghouse Officer,
Office of Federal Grant Management and
Reporting, 301 West Pearl Street, Jackson,
Mississippi 39203, Telephone (601) 960-
2174

Missouri

Ms. Lois Pohl, Federal Assistance
Clearinghouse, Office of Administration,
P.O. Box 809, Room 430, Truman Building,
Jefferson City, Missouri 65102, Telephone
(314) 751-4834

Nevada

Department of Administration, State
Clearinghouse, Capitol Complex, Carson
City, Nevada 89710, Telephone (702) 687-
4065, Attention: Ron Sparks,
Clearinghouse Coordinator

New Hampshire

Mr. Jeffrey H. Taylor, Director, New
Hampshire Office of State Planning, Attn:
Intergovernmental Review, Process/James
E. Bieber, 2½ Beacon Street, Concord, New
Hampshire 03301, Telephone (603) 271-
2155

New Jersey

Gregory W. Adkins, Acting Director, Division
of Community Resources, N.J. Department
of Community Affairs, Trenton, New Jersey
08625-0803, Telephone (609) 292-6613
Please direct correspondence and
questions to: Andrew J. Jaskolka, State

Review Process, Division of Community
Resources, CN 814, Room 609, Trenton, New
Jersey 08625-0803, Telephone (609) 292-
9025.

New Mexico

George Elliott, Deputy Director, State Budget
Division, Room 190, Bataan Memorial
Building, Santa Fe, New Mexico 87503,
Telephone (505) 827-3640, FAX (505) 827-
3006

New York

New York State Clearinghouse, Division of
the Budget, State Capitol, Albany, New
York 12224, Telephone (518) 474-1605

North Carolina

Mrs. Chrys Baggett, Director, Office of the
Secretary of Admin., N.C. State
Clearinghouse, 116 W. Jones Street,
Raleigh, North Carolina 27603-8003,
Telephone (919) 733-7232

North Dakota

N.D. Single Point of Contact, Office of
Intergovernmental Assistance, Office of
Management and Budget, 600 East
Boulevard Avenue, Bismarck, North
Dakota 58505-0170, Telephone (701) 224-
2094

Ohio

Larry Weaver, State Single Point of Contact,
State/Federal Funds Coordinator, State
Clearinghouse, Office of Budget and
Management, 30 East Broad Street, 34th
Floor, Columbus, Ohio 43266-0411,
Telephone (614) 466-0698

Rhode Island

Mr. Daniel W. Varin, Associate Director,
Statewide Planning Program, Department
of Administration, Division of Planning,
265 Melrose Street, Providence, Rhode
Island 02907, Telephone (401) 277-2656
Please direct correspondence and
questions to: Review Coordinator, Office of
Strategic Planning.

South Carolina

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Texas

Mr. Thomas Adams, Governor's Office of
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Austin, Texas 78711, Telephone (512) 463-
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Utah

Utah State Clearinghouse, Office of Planning
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116 State Capitol, Salt Lake City, Utah
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Vermont

Mr. Bernard D. Johnson, Assistant Director,
Office of Policy Research & Coordination,
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West Virginia

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Mr. William C. Carey, Federal/State
Relations, Wisconsin Department of
Administration, 101 South Webster Street,
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Wyoming

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Guam

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Budget and Management Research, Office
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Northern Mariana Islands

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Puerto Rico

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Virgin Islands

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Management and Budget, #41 Norregade
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Please direct correspondence to: Linda
Clarke, Telephone (809) 774-0750.

BILLING CODE 4184-01-P

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, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR Part 76, certifies to the best of its knowledge and believe that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal Department or agency;

(b) have not within a 3-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 indicted 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 3-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

The inability of a person to provide the certification required above will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the Department of Health and Human Services (HHS) 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.

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

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions (To Be Supplied to Lower Tier Participants)

By signing and submitting this lower tier proposal, the prospective lower tier participant, as defined in 45 CFR Part 76, 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 from participation in this transaction by any federal department or agency.

(b) where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal.

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

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.

Statement for Loan Guarantees 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

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.

[FR Doc. 95-15585 Filed 6-23-95; 8:45 am]

BILLING CODE 4184-01-P

Food and Drug Administration

[Docket No. 95N-0182]

KV Pharmaceutical Co.; Proposal To Withdraw Approval of Two Abbreviated New Drug Applications and One Abbreviated Antibiotic Drug Application; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of two abbreviated new drug applications (ANDA's) and one abbreviated antibiotic application (AADA) held by KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144 (KV). The grounds for the proposed withdrawals are (1) that the applications contain untrue statements of material fact; and (2) that based upon new information evaluated together with the evidence available when the applications were approved, there is a lack of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

DATES: A hearing request is due on July 26, 1995; data and information in

support of the hearing request are due August 25, 1995.

ADDRESSES: A request for a hearing, supporting data, and other comments should be identified with Docket No. 95N-0182 and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Harry T. Schiller, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On February 4, 1992, FDA attempted to inspect KV to determine whether or not the firm was following current good manufacturing practice (CGMP) regulations. The firm, however, refused to provide necessary records as required under the Federal Food, Drug, and Cosmetic Act (the act). (See sections 505(k) and 704 of the act (21 U.S.C. 355(k) and 21 U.S.C. 374).) The agency, therefore, obtained inspection warrants and inspected KV between March 11 and April 23, 1992. Despite the inspection warrants, KV failed to provide all of the documents requested. FDA conducted another inspection of KV between July 31 and November 3, 1992.

During the two 1992 inspections, the agency compared documents and data found at the firm with records previously submitted to FDA in support of KV's AADA and ANDA applications. The agency discovered that KV had submitted false and misleading information in the following applications:

1. AADA 62-047, Erythromycin Ethylsuccinate Oral Suspension, 200 and 400 milligrams (mg);
2. ANDA 71-929, Disopyramide Phosphate Extended Release Capsules, 100 mg; and
3. ANDA 86-538, Nitroglycerin Extended Release Capsules, 2.5 mg.

In support of the AADA and the two ANDA's listed above, KV submitted analytical data necessary for approval and continued approval of the applications, including stability data. During its inspections of KV, the agency discovered documents that showed that KV had made untrue statements in some of the stability data it had submitted in supplements and amendments to the applications. The documents also showed that KV had made untrue statements concerning stability data in

annual reports submitted to the applications.

In letters dated June 1, 1993, and November 12, 1993, FDA informed KV that the agency intended to downgrade the therapeutic equivalency rating of the products listed above in the agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") and to begin the administrative procedures necessary to withdraw approval of the products. Accordingly, as explained below, the Director of the Center for Drug Evaluation and Research (the Director) is proposing to withdraw approval of the products' applications.

II. Evidence That the Applications Contain Untrue Statements of Material Fact

The first ground for withdrawing the AADA and two ANDA's listed above is that the applications contain untrue statements of material fact (21 U.S.C. 355(e)(5)). This section presents FDA's general comments on untrue statements and materiality, and then sets forth the specific false and misleading information in the three abbreviated applications.

A. Untrue Statements

The untrue statements submitted by KV in its drug applications include both stability test results that are inconsistent with stability test results retained by the firm and selective or incomplete reporting of stability data.

1. Conflicts Between Information Submitted to the Agency and Information Retained by the Firm

The first type of untrue statement submitted in the drug applications listed above consists of data that differ from data and other primary source information discovered at the firm. The agency concludes in such cases that, in the absence of a satisfactory explanation, the discrepant information in the application is untrue.

Information in an AADA or ANDA, including the facts and data covered by this notice, is generally derivative information. Such information is often a restatement, summary, or copy of original data or other underlying information such as that found in laboratory notebooks not specifically included in the application. The agency believes that original or underlying data generally have a higher degree of reliability because they are the primary sources of the information that are usually created contemporaneously with the event the information describes. Restated, summarized, or copied information submitted in the