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The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 8, 2001.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 01-12003 Filed 5-11-01; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[Program Announcement No. ACYF-CCB-2201-04]

#### Child Care Policy Research Discretionary Grants

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

**ACTION:** Announcement of the availability of funds and request for applications for Field Initiated Child Care Research Projects, Child Care Research Scholars, and State Child Care Data and Research Capacity Projects.

**SUMMARY:** The purpose of this program announcement is to announce the availability of \$3.7 million in fiscal year 2001 funds for child care research, demonstration, and evaluation activities. Grants will be funded in the following three priority areas: (1) Field Initiated Child Care Research Projects; (2) Child Care Research Scholars; and (3) State Child Care Data and Research Capacity Projects. Universities and colleges, public agencies, non-profit organizations, and for-profit organizations agreeing to waive their fees are invited to submit applications for Field Initiated Child Care Research Projects. Accredited universities and colleges may submit a Child Care Research Scholar application on behalf of a doctoral student conducting dissertation research on a child care policy topic. Child Care and Development Fund Lead Agencies seeking to improve their capacity for data analysis and policy-relevant research are invited to submit applications for the State Child Care Data and Research Capacity Projects.

Projects funded under each of the priority areas are expected to address critical questions with implications for children and families, especially low-income working families and families transitioning off welfare. In addition, projects will contribute to a comprehensive research agenda designed to increase the capacity for child care research at the national, State, and local levels and promote better linkages among research, policy, practice, and outcomes for children and families.

**Statutory authority:** The Child Care and Development Block Grant Act of 1990 as amended (CCDBG Act); section 418 of the Social Security Act; Consolidated Appropriations Act, 2001 (P.L. 106-554).

**DATES:** The closing date for submission of applications is June 28, 2001. Mailed applications postmarked after the closing date will be classified as late.

**Note:** The full announcement, including all the Standard Federal Forms can be downloaded from the Internet at <http://www.acf.dhhs.gov/programs/ccb> or by contacting ACYF's Operations Center at 1-800-351-2293. For each priority area, the required Standard Federal Forms are identified under "Project Description and Application Requirements."

**Notice of Intent to Submit Application:** If you intend to submit an application, please contact ACYF's Operations Center at 1-800-351-2293 with the number and title of this announcement; your organization's name and address; and your contact person's name, phone number, fax number, and Email address. The information will be used to determine the number of expert reviewers need to evaluate applications and to update the mailing list for program announcements.

**FOR FURTHER INFORMATION CONTACT:** For information about the application process contact ACYF Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, VA 22209, Phone: 800-351-2293. For program information contact Dr. Ivelisse Martinez-Beck, Policy Fellow, Administration for Children and Families, Child Care Bureau, Room 2046, Mary E. Switzer Building, 330 C Street, SW., Washington, DC 20447, Phone: 202-690-7885, Fax: 202-690-5600, Email: [imartinezbeck@acf.dhhs.gov](mailto:imartinezbeck@acf.dhhs.gov). or Dr. Patricia L. Divine, Program Specialist, Administration for Children and Families, Child Care Bureau, Room 2046, Mary E. Switzer Building, 330 C Street, SW., Washington, DC 20447, Phone: 202-690-6705, Fax: 202-690-5600, Email: [pdivine@acf.dhhs.gov](mailto:pdivine@acf.dhhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### Priority Area 1: Field Initiated Child Care Research Projects

##### A. Number of Awards

Approximately 7-10 grants will be awarded during fiscal Year 2001, for an initial budget period of twelve months, subject to the availability of funds and results of the evaluation process.

##### B. Project Duration, Funding Levels and Budget Periods

This priority area is soliciting applications for project periods up to three years. Awards, on a competitive basis, will be for a one-year budget period, although project periods may be for three years. Application for continuation grants funded under these awards beyond the one-year budget period, but within the three year project period, will be entertained in subsequent years on a non-competitive basis, subject to the availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the government. Significant findings by the end of the first budget period will be necessary to demonstrate satisfactory progress on the part of the grantee.

Funding for Field Initiated Child Care Research Projects will range between \$150,000 and \$250,000 for the first budget period and up to \$200,000 per year (12 months) in subsequent periods.

##### C. Federal State

To maximize the Federal investment in Field Initiated Child Care Research Projects and in the interest of project sustainability, a financial commitment by the applicant organization (or other participating entities) is required. The Grantee must provide at least 20 percent of the total approved cost of the project. The total approved cost is the sum of the Federal share and the non-Federal share. Therefore, a project requesting \$250,000 for the first budget period must include a match of at least \$62,500. A project receiving the maximum total of \$650,000 for the three-year project period must include a match of at least \$162,500 for the three-year project period. Applicants are encouraged to meet their match requirements through cash contributions. However, the non-Federal share may also be in-kind contributions of staff time, employee benefits, facilities, utilities, equipment, materials, supplies or other forms of project support. Grantees will be held accountable for the commitment of non-Federal resources and failure to provide the required amount will result in

disallowance of unmatched Federal funds.

#### *D. Eligible Applicants*

Eligible applicants include public agencies, non-profit organizations, and for-profit entities that agree to waive their fees.

1. Public agencies include state or local child care agencies; education agencies, welfare or other human services agencies, public schools, colleges and universities; and other public agencies with an interest in child care.

2. Non-profit agencies include, but are not limited to, community child care and early childhood programs, child care resource and referral programs, professional organizations, schools, colleges and universities, civic and community groups, and foundations.

3. For-profit entities include, but are not limited to, child care businesses, private research corporations, and other profit-making organizations. These entities are only eligible to receive a grant directly if they agree to waive their fees. However, they may participate in projects as subcontractors, sub-grantees, or consultants without such a waiver.

#### **Criterion 1: Objectives and Need for Assistance (Maximum of 20 points)**

In this section, applicants demonstrate their understanding of the relevant literature on critical issues and existing knowledge, describe their objectives, and demonstrate the significance of their proposal.

Applicants are expected to show how their proposal will address the Child Care Bureau's research agenda and priorities, answer key questions, and contribute to the child care research infrastructure. Specifically, applicants are expected to demonstrate a command of the policy and research literature in child care, as well as emerging issues. The proposal is expected to demonstrate understanding of current policies and programs, to show how the proposed research would further understanding, and to suggest practical applications which might be derived from the findings.

Applications should clearly show how the research would build on the current knowledge base and contribute to policy, practice, and future research. Applicants are asked to consider the significance, reliability, and validity of existing data pertaining to key questions. In addition, applicants should identify important gaps in the literature and areas in which findings are contradictory or ambiguous. It will also be important to consider what demographic, economic, and social data

are available as a context for the proposed child care research. A bibliography of relevant literature must be supplied.

#### **Criterion 2: Approach (Research Design and Methodology) (Maximum of 30 Points)**

This section of the Project Narrative Statement requires that the applicant describe the technical approach for addressing issues and achieving objectives described in Criterion 1 above. In this section the applicant should clearly demonstrate their ability to produce significant and usable results within the first 12-month budget period.

The methodological discussion must include technical details of the proposed research design, including (as relevant): (1) Conceptual framework for the research; (2) research questions, hypotheses, and variables; (3) data sources and sampling plan; (4) new data on human subjects; (5) administrative data; (6) secondary analysis of existing data sets; (7) linkages with other research; (8) data collection; (9) data processing and statistical analysis; and, (10) product development and information dissemination. Qualitative studies with well-defined methodology are invited as well as those that use quantitative methodology. As part of the design section, applicants should discuss the strengths and limitations of all proposed approaches and techniques. Applicants are also asked to provide a flow chart or table showing interrelationships among the proposed research issues, questions, variables, and data elements.

#### **Criterion 3: Approach (Management Plan) (Maximum of 10 Points)**

The Management Plan is expected to describe a sound and workable plan of action for how the proposed project will be carried out. This section should detail how the project will be structured and managed.

Applicants should provide a diagram showing the organizational structure of the project and the functional relationships among components. If the project is a collaborative, describe how the project will be managed by the lead organization to ensure that members of the collaborative operate as a cohesive research team and that cross-cutting goals of the project are carried out efficiently and cost-effectively. Describe the make-up and role of any steering or management committees, technical work groups, advisory panels, and other coordinating bodies.

Produce a project management chart that lays out sequence and timing of the major tasks and subtasks, including

startup activities such as staffing and procurement of services, responsibilities and time commitments to staff, important milestones, reports, and completion dates. Explain how timeliness of activities will be ensured, how quality control will be maintained, and how costs will be controlled.

Applicants should discuss their management of the project as a whole, and the management and coordinating roles of any collaborating entities. Discuss potential problems or difficulties with the proposed management approach, including factors which may affect the quality of the research or its outcomes, may undermine the ability of different entities to collaborate effectively, and may hinder the early spring, review and dissemination of information.

#### **Criterion 4: Staff and Position Data (Maximum of 20 Points)**

In this section, applicants must provide evidence that project staff have the experience, expertise and commitment of sufficient time to carry out the proposed project on time, within budget, and with a high degree of quality.

Identify all key staff positions for this project, the professional requirements for each, the proportion of time staff holding these positions will be committed to the project, the period of time they will be employed, and whether continued employment will be dependent solely on the funds to be awarded under this announcement.

Include a position description for each key position, outlining the qualifications necessary to carry out the duties and responsibilities of each. Include letters of commitment from any key individuals who have been selected but not yet hired. Describe the makeup of the data collection team, what expertise will be represented, and how individuals will be selected. Identify all proposed consultants or advisors, document their expertise, and describe how their services will be utilized. Include letters of commitment or intent if possible. And, identify the authors of the proposal and describe their continuing role in the project, if funded.

#### **Criterion 5: Organizational Profiles (Maximum of 10 Points)**

In this section, the applicant must demonstrate that the official grantee has the organizational capacity and fiscal resources to successfully carry-out the project on time and to a high standard of quality, including the capacity to resolve a wide variety of technical and management problems that may occur.

Provide evidence of sufficient organizational resources to ensure successful project management, compliance with terms and conditions of the grant, and oversight of the proper use of Federal funds.

If the project is a collaborative, provide evidence that all collaborators have the ability, willingness and flexibility to collaborate effectively with one another in carrying out the proposed project. Include examples of past or current collaborations that demonstrate the ability to carry out collaborative research. Describe how each entity was included in the planning of the project. Include letters of specific commitment or support from each entity. Describe all cooperative agreements, subcontracts and other formal relationships within the collaborative. Entities who will provide access to data or records must provide a letter stipulating the terms of their agreement with the researchers. Describe the future commitment each entity will make to ensure success of the collaboration as it evolves. Include a separate two-page organizational capability statement for each participating entity that documents the entity's ability to carry out its assigned roles and functions.

Describe the relationship between this project and other relevant work planned, anticipated or underway by the applicant or its collaborators. Include funding sources for work in progress. Provide a list of research and financial partners including the name and address of each organization, the names of its director and primary contact for this proposal, and the telephone, fax and internet numbers of each.

#### Criterion 6: Budget and Budget Justification (maximum of 10 points)

Describe the nature and extent of financial participation from all sources during the proposed project period. Present a detailed budget for each 12-month interval of the proposed project period, i.e., the 12 month budget period to be funded under this announcement and subsequent budget period that may be funded under a non-competing continuation process. Include a detailed budget narrative that describes and justifies line item expenses within the object class categories listed on the Standard Form 424A. (Line item allocations and justification are required for both Federal and non-Federal funds.) If project funds will be subcontracted, a detailed budget for the use of those funds must be also included. In estimating costs, applicant should consider down time due to staff

vacancies, administrative processes, etc. The budget should include funds to allow key representatives from Field Initiate Child Care Research Projects to participate in the Child Care Bureau Annual Policy Research Meeting in Washington, DC.

Describe the extent to which funds, staff time, in-kind services, and other resources have been committed to the research effort during the planning period. Describe what other resources are expected to help support the proposed research, including existing commitments and negotiations in progress. Describe anticipated efforts to obtain other funding partners throughout the project.

#### Priority Area 2: Child Care Research Scholars

##### A. Number of Awards

Up to 5 scholarships will be awarded. No individual educational institution will be funded for more than one candidate unless applications from different universities or colleges do not qualify for support.

##### B. Project Period

The project period will be for a period of up to 24 months (9/30/01–9/29/03). For 24 month projects, the first 12 months will be funded through this competition. The subsequent year awards (12 months) will be considered on a non-competitive basis subject to the availability of funds from future appropriations, satisfactory progress of the grantee, and a determination that continued funding is in the best interest of the government. Significant findings by the end of the first budget period will be necessary to demonstrate satisfactory progress on the part of the grantee. A subsequent year award will not be approved if the student has graduated by the end of the first year.

##### C. Funding Levels

Up to \$30,000 will be awarded to each successful applicant for a 12-month budget period. If the applicant expects to receive a doctorate by the end of the first one-year budget period, the application should request funding for a single grant period.

##### D. Matching Requirements and Non-Federal Share

There are no matching requirements.

##### E. Maximum Federal Share

The maximum federal share is \$30,000 for the first 12-month budget period and \$20,000 for one subsequent 12-month period.

All monies must be used for the dissertation research including required

personnel costs, travel, and other expenses directly related to the research.

#### F. Eligible Applicants

Eligible applicants include universities or colleges on behalf of doctoral candidates conducting dissertation research on a child care topic consistent with the research goals described in Part II of the full announcement, and who anticipate completing the child care-related dissertation within the two-year scholarship period.

To be eligible to administer the grant on behalf of the student, the institution must be fully accredited by one of the regional accrediting commissions recognized by the Department of Education. Although the faculty advisor will be listed as the Principal Investigator, this grant is intended for dissertation work being conducted by a doctoral candidate. Information about both the graduate student and the student's faculty advisor is required as part of this application. Any resultant grant award is not transferable to another student.

#### Criterion 1: Objectives and Need for Assistance (Maximum of 20 Points)

The extent to which the application reflects a solid understanding of critical issues, information needs, and research goals.

- The extent to which the conceptual model, research issues, objectives and hypotheses are significant, well formulated and appropriately linked, reflect the Child Care Bureau's research agenda and priorities, and will contribute new knowledge and understanding.

- The extent to which the proposed project framework is appropriate, feasible, and would significantly contribute to the importance, comprehensiveness, and quality of the proposed research.

- The effectiveness with which the proposal articulates the current state of knowledge relative to issues being addressed, including: critical child care issues and the complex interrelationships among major variables; the significance of these issues and variables for child care policies and programs; how current knowledge would be brought to bear on the proposed research; and how the research would benefit various audiences.

- The importance of research priorities identified for the first budget period, the degree to which early findings would be useful for policy and practice, and the significance of these

data for the ongoing research goals if the project is continued beyond the first 17-month period.

**Criterion 2: Approach (Research Design and Methodology) (Maximum of 40 Points)**

The extent to which the applicant's proposed research design:

- Appropriately links critical research issues, questions, variables, data sources, samples, and analyses;
- Employs technically sound and appropriate approaches, design elements and procedures;
- Reflects sensitivity to technical, logistical, cultural and ethical issues that may arise;
- Includes realistic strategies for the resolution of difficulties;
- Adequately protects human subjects, confidentiality of data, and consent procedures, as appropriate;
- Includes an effective plan for the dissemination and utilization of information by researchers, policy-makers, and practitioners in the field; and,
- Effectively utilizes collaborative strategies, as appropriate to the project goals and design.

**Criterion 3: Approach (Management Plan) (Maximum of 20 Points)**

The extent to which the project summary provides a management plan that:

- Presents a sound, workable and cohesive plan of action demonstrating how the work would be carried out on time, within budget and with a high degree of quality;
- Includes a reasonable schedule of target dates and accomplishments;
- Presents a sound administrative framework for maintaining quality control over the implementation and ongoing operations of the study; and,
- Demonstrate the ability to gain access to necessary organizations, subjects, and data.

**Criterion 4: Organizational Profile (Applicant Qualifications and Commitment) (maximum of 10 points).**

The extent to which the applicant:

- Demonstrates competence in areas addressed by the proposed research, including relevant background, experience, training and work on related research or similar projects; and
- Demonstrates necessary expertise in research design, sampling, field work, data processing, statistical analysis, reporting, and information dissemination.

**Criterion 5: Budget and Budget Justification (maximum of 10 points).** The extent to which proposed project costs are reasonable, the funds are appropriately allocated across component areas, and the budget is sufficient to accomplish the objectives. The budget should include funds to allow the research scholar to participate in the Child Care Bureau's Annual Policy Research Meeting in Washington, DC.

**Priority Area 3: State Child Care Data and Research Capacity Projects**

*A. Eligible Applicants*

State and Territorial Lead Agencies administering child care programs under the Child Care and Development Block Grant (CCDBG) of 1990 as amended.

*B. Number of Awards*

Five to six State Child Care Data and Research Capacity Grants will be funded in Fiscal Year 2001, subject to availability of funds and results of the evaluation process.

*C. Project Duration, Funding Levels and Budget periods*

State Child Care Data and Research Capacity Grants will be awarded for project periods of up to three years. The Child Care Bureau expects to invest up to \$250,000 during the initial 12-month funding period for each project. Non-competitive applications for continuation of State Child Care Data and Research Capacity Projects will be considered in fiscal years 2002 and 2003 with up to \$250,000 per project being available for a 12-month period. Applications for continuation grants funded beyond the 12-month budget period, but within the 36-month project period, will be entertained in the subsequent year on a noncompetitive basis, subject to the availability of funds from future appropriations, satisfactory progress of the grantee, and a determination that continued funding is the best interest of the government.

*D. Federal Share*

To maximum the Federal investment in the State Child Care Data and Research Capacity Projects and in the interest of project sustainability, a financial commitment by the applicant organization (or other participating entity) is required. The grantee must provide at least 20 percent of the total approved cost of the project. The total approved cost is the sum of the Federal share and the non-Federal share. Therefore, a project requesting \$250,000 per budget period must include a match of at least \$62,500. A project receiving

the maximum \$750,000 during the three-year project period must include a match of at least \$187,500 for the three-year project period. Applicants are encouraged to meet their match requirements through cash contributions. However, the non-Federal share may be in-kind contributions. Grantees will be held accountable for the commitment of non-Federal resources and failure to provide the required amount will result in a disallowance of unmatched Federal funds.

**Criterion 1: Objectives and Need for Assistance (35 Points)**

In this section, applicants are expected to provide a clear and comprehensive description of their agency's current capacity to collect, analyze and report child care administrative data. This description should include data collection, analysis and reporting required by the State and Federal governments, as well as reports designed for the legislature and other constituencies. Applicants are encouraged to provide a description of the internal and external information needs of the agency, constituencies for information, and the types of data required or requested by these agencies, organizations or groups.

Applicants are expected to describe the current structure, management, and process for collecting, analyzing and reporting data. This description should include a consideration of the strengths and weaknesses of the current operating system and analytic components. The need for assistance should be clearly stated.

In addition, applicants should describe the research and evaluation that would be conducted by the proposed analysis unit. Applicants are encouraged to identify specific research questions to be addressed by the unit and explain how the agency's data systems would be used to answer these questions.

**Criterion 2: Approach (30 points)**

In this section, applicants are expected to describe in detail how they will implement the proposed analysis unit, improve the State's capacity for collection, analysis, interpretation, and reporting of data, and conduct child care policy-relevant research. Applicants are advised to present their assessment of the advantages and disadvantages of an in-house analysis unit versus a contractual partner. Applicants should describe in detail why they have selected one approach over the other. The justification should include a description of how the chosen

approach will mesh with current information demands, operations and procedures, management structure, staffing and other resources.

Regardless of the approach selected (in-house or contractual), the applicant is expected to present an implementation plan and describe in detail how the unit will be established, managed, operated and evaluated. This section should also include a plan for sustaining the unit after Federal funding has ceased.

This section of the Project Narrative Statement also requires that the applicant describe the technical approach for addressing issues and achieving the objectives described in Criterion above. This should include a detailed plan that identifies goals and objectives, relates those goals and objectives to the strengths and weakness identified regarding the State's current methods and systems used to collect and compile administrative data, and provides a work plan identifying specific activities necessary to accomplish the stated goals and objectives. The plan must demonstrate that each of the project objectives and activities support the needs identified and can be accomplished with the available or expected resources during the proposed project period.

For any research that is proposed within the project period, a methodological discussion must be provided that includes technical details of the proposed research design, including: (1) conceptual framework for the research; (2) research questions, hypotheses and variables; (3) data sources; (4) linkages with other research; (5) data processing and statistical analysis; and (6) product development and information dissemination. (For more details on the information required in this section, see Criterion 2, Research Design and Methodology, in Evaluation Criteria for Field Initiated Child Care Research Projects.)

#### Criterion 3: Organization Profiles (25 Points)

Applicants need to demonstrate that they have the capacity to implement the proposed project. This criterion consist of the three broad topics: (1) Management plan, (2) staff qualifications and commitment, and (3) organizational capacity and resources.

#### Management Plan

##### Overview

Applicants are expected to present a sound and feasible management plan for implementing the analysis unit. This

section should detail how the unit will be structured and managed, how the timeliness of activities will be ensured, how quality control will be maintained, and how costs will be controlled. The role and responsibilities of the lead agency should be clearly defined and, if appropriate, applicants should discuss the management and coordination of activities carried out by any partners, subcontractors and consultants.

Applicants are required to provide a plan that describes the role, responsibilities and time commitments of each proposed staff position, including consultants, subcontractors and/or partners. The plan should include a list of organizations and consultants who will work with the program along with a short description of the nature of their effort or contribution.

Applicants are expected to have the project fully staffed and ready for implementation as quickly as possible after notification of the grant award. Therefore, strategies for ensuring timely staffing and implementation should be clearly and succinctly presented in the management plan. The narrative should include a description of the timeline for hiring and procurement in the State, and methods that the applicant will use to expedite the process.

Applicants are also expected to produce a timeline that presents a reasonable schedule of target dates, accomplishments and deliverables by quarter. The timeline should include the sequence and timing of the major tasks and subtasks, important milestones, reports, and completion dates. The proposal should also discuss factors that may affect project implementation or the outcomes and present realistic strategies for the resolution of these difficulties. For instance, downtime due to staff vacancies at start should be reflected. Additional, if appropriate, applicants should present a plan for training project staff, as well as stuff of cooperating organizations.

#### Staff Qualifications and Commitment (10 Points)

##### Overview

In this section, applicants should describe the qualifications of the project manager and key staff, including analysts who will staff the analysis unit and the positions they will fill. Applicants are also expected to describe the educational background and professional experience of other professionals who will form the interdisciplinary analysis unit or organization. (Brief resumes should be provided.) The proposed staff should

include persons with educational backgrounds and professional experiences in early childhood services, child development, social work, public policy, economics and other social science disciplines such that the analysis unit or organization will be able to conduct research on a broad range of child care issues and approaches.

#### Organizational Capacity and Resources (5 Points)

##### Overview

Applicants must show that they have the organizational capacity and resources to form, manage, operate, evaluate and sustain an analysis unit, including the capacity to resolve a wide variety of technical and management problems that may occur. If the proposal involves partnering and/or subcontracting with other agencies/ organizations, then the proposal should include an organizational capability statement for each participating organization documenting the ability of the partners/and or subcontractors to carry out their assigned roles and functions.

#### Criterion 4: Budget and Budget Justification (10 Points)

Applicants are expected to present a budget with reasonable project costs, appropriately allocated across component areas, and sufficient to accomplish the objectives. They should demonstrate that costs for the proposed project are reasonable and justified in terms of the proposed tasks and the anticipated results and benefits. Applicants should refer to the budget information as presented on Standard Forms 424 and 424A and the budget justification.

The proposed budget should include sufficient funding to cover travel expenses for a key person from the project and the evaluator to attend two two-day meetings of grantees in the Washington DC area hosted by the Child Care Bureau. Attendance at these meetings is a grant requirement.

#### Required Notification of the State Single Point of Contact

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

\* All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, American Samoa and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-four jurisdictions need take no action regarding 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 accommodation or explain rule.

When comments are submitted directly to ACF, they should be addressed to: Marguerite Pridgen, Office of Grants Management, 330 C Street, SW., Washington, DC 20447, Attn: Child Care Policy Research Discretionary Grants. A list of the Single Points of Contact (SPOCs) for each State and Territory can be found on the following web site: <http://www.whitehouse.gov/omb/grants/spoc.html>.

The Catalog of Federal Domestic Assistance number for all priority areas is 93.647.

Dated: May 8, 2001.

**James A. Harrell,**

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

[FR Doc. 01-12010 Filed 5-11-01; 8:45 am]

**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98E-0476]

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

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

**ACTION:** Notice.

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

**ADDRESSES:** Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Regulatory Policy Staff (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5645.

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

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the

Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product Infergen (interferon alfacon-1 or consensus interferon). Infergen is indicated for the treatment of chronic hepatitis C virus (HCV) infection in patients 18 years of age or older with compensated liver disease who have anti-HCV serum antibodies and/or presence of HCV RNA (ribonucleic acid). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Infergen (U.S. Patent No. 4,695,623) from Amgen, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 9, 1998, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Infergen represented the first permitted commercial marketing or use of the product. Later, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Infergen is 4,394 days. Of this time, 3,849 days occurred during the testing phase of the regulatory review period, while 545 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* September 27, 1985. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 27, 1985.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* April 10, 1996. FDA has verified the applicant's claim that the product license application (PLA) for Infergen (PLA 96-0486) was initially submitted on April 10, 1996.

3. *The date the application was approved:* October 6, 1997. FDA has verified the applicant's claim that PLA 96-0486 was approved on October 6, 1997.