disclosure of client-identifying information;

c. Obtain informed client consent by explaining the risks of disclosure and the recipient's policies and procedures for preventing unauthorized disclosure;

d. Provide written assurance to this effect including copies of relevant policies; and

e. Obtain assurances of confidentiality by agencies to which referrals are made.

Assurance of compliance with these and other processes to protect the confidentiality of information will be required of all recipients. A Department of Health and Human Services (DHHS) certificate of confidentiality may be required for some projects.

G. Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where a clear and compelling rationale exists that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47949–47951, dated Friday, September 15, 1995.

H. Capability Assessment

Some applicants may be required to participate in a fiscal Recipient Capability Assessment prior to the award of funds.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Number 0937–0189) must be submitted to Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E–13, Atlanta, Georgia 30305, on or before May 20, 1997.

1. Deadline: Applications shall be considered as meeting the deadline if they are either;

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the special emphasis panel review committee. For proof of timely mailing, applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.

2. Late Applications:

Applications that do not meet the criteria in 1.a. or 1.b. above are considered late. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to reference Announcement 727. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6535 or internet address <jcw6@cdc.gov>.

Programmatic technical assistance may be obtained from Chester L. Pogostin, D.V.M., M.P.A., Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control, Division of Violence Prevention, Mailstop K–60, Atlanta, Georgia 30333, telephone (770) 488–4279; Internet: clp3@cdc.gov.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is http://www.cdc.gov.

CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 727 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full report; Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report; Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington D.C., 20402–9325, telephone (202) 512–1800.

Dated: March 10, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–6497 Filed 3–13–97; 8:45 am]

BILLING CODE 4163–18–P

[Announcement Number 731]

Research Projects for Health Promotion for Persons With Disabilities and Prevention of Secondary Conditions; Notice of Availability of Funds for Fiscal Year 1997

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 competitive grant and cooperative agreement funds. Part 1 of this Announcement will support research grants to: (a) Measure the magnitude of secondary conditions in specified populations of persons who have a disability; (b) determine the risk and protective factors that contribute to or avert the occurrence of secondary conditions; (c) conduct and measure the effectiveness of health promotion interventions designed to prevent secondary conditions; and/or (d) understand the prevention effectiveness and cost-effectiveness of interventions. Part 2 of this Announcement will support one cooperative agreement project to prevent the occurrence of pressure sores and other selected secondary conditions among persons with spinal cord injury.

CDC is committed to achieving the health promotion and disease prevention objectives described in ''Healthy People 2000,'' a national activity to reduce morbidity and mortality and improve the quality of life. This Announcement is related to the Healthy People 2000 category of Preventive Services. (For ordering a copy of ''Healthy People 2000,'' see the section Where to Obtain Additional Information.)

Authority

This program is authorized by Section 301(a) (42 U.S.C. 241(a)) and Section 317 (42 U.S.C. 247b) of the Public Health Service Act, as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of

all tobacco products. Public Law 103–227, the Pro-Children Act of 1994 prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants for this program are public and private non-profit entities, including universities; university-affiliated systems including not-for-profit medical centers; research institutions and rehabilitation hospitals; State health departments and other related State government agencies; disability service groups such as advocacy and voluntary organizations and independent living centers; and federally recognized Indian Tribal Governments.

Note: An organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant, contract, loan, or any other form.

Availability of Funds

This Announcement has two separate components as noted in the INTRODUCTION section. Under Part 1, it is anticipated that approximately $1,800,000 will be available in FY 1997 to support 6 to 8 research grant projects, with an expected range of awards from $220,000 to $280,000 each. Under Part 2, it is estimated that approximately $250,000 will be available in FY 1997 to support one cooperative agreement to prevent the occurrence of pressure sores and other selected secondary conditions among persons with spinal cord injury. Awards are expected to be made on or before August 1, 1997, for a twelve-month budget period within a project period of up to three years. Funding estimates are subject to change, including funds to be awarded in continuation years based on documented progress toward objectives, the quality of continuation year work plans, evidence of cost-sharing, and the availability of funds.

This program has no statutory matching requirement. However, applicants should document their financial support for a portion of project costs, such as salaries for key staff and tangible contributions by collaborating agencies. Applicants should also demonstrate their capacity to increase cost-sharing over time, and identify other funding sources to assist in project activities.

Use of Funds

Grant funds may be used to support personnel services, supplies, equipment, travel, subcontracts, and other services directly related to project activities consistent with the approved scope of work. Project funds may not be used to supplant other available applicant or collaborating agency funds, for construction, for lease or purchase of facilities or space, or for patient care. Project funds may not be used for individualized preventive measures (direct patient support) such as for wheelchairs, medical appliances, or assistive technology unless specifically approved by the funding agency.

Purpose

The purpose of grant awards under Part 1 is to develop better understanding of the secondary conditions that occur among prescribed groups of persons with disabilities. These awards will allow grantees to measure the risk factors and protective factors for preventing secondary conditions, and to assess the cost- and prevention-effectiveness of interventions targeted to the needs of persons with disabilities.

The purpose of the Part 2 cooperative agreement award is to design, conduct, and report the findings of a model project to prevent pressure sores and other selected secondary conditions among persons with spinal cord injury. This project should explore the feasibility of a home-based intervention; e.g., a public health nurse visitation program addressing medical, social, and environmental factors associated with the development of pressure sores and other selected secondary conditions.

Projects receiving funds for either Part 1 or Part 2 are expected to design, document, and publish the results of their research in a manner that promotes generalizability so that academic institutions, State and local agencies, disabilities service programs, and other organizations concerned with public health and health promotion programs for persons with disabilities and rehabilitation can benefit. Project activities must provide evidence that all project programs will involve and be accessible to persons with disabilities.

Background—General

The CDC Office on Disability and Health (proposed, current name-Disabilities Prevention Program) has provided grant funds to universities, rehabilitation hospitals, and State agencies since 1988 to increase understanding of the disabling process and conduct research to prevent secondary conditions. Those research grants have focused on the frequency, severity, cost, and significance of a specific, or a range of secondary conditions associated with a prescribed primary disability (e.g., spinal cord injury, traumatic brain injury, fetal alcohol syndrome, cerebral palsy, and the late effects of polio).

Background for Part 1

Part 1 of the research emanating from this Announcement is designed to examine, understand, and document the participation of persons with disabilities within their social environment as related to a particular disability domain. Disability domains are categories of activities that individuals perform in everyday life. Applicants should propose grant activities in at least one of the following disability domains: (1) Mobility (locomotion); (2) personal care/home management; (3) communication; and (4) learning. Descriptions and examples within these disability domains are as follows:

1. *Mobility* (locomotion) refers to an individual's ability to perform distinctive activities associated with moving; both himself and objects, from place to place. Examples of underlying conditions or diagnoses include spinal cord injury, cerebral palsy, arthritis, lower limb loss, blindness, or stroke. Secondary conditions may include urinary tract infections, cardiovascular deficit due to sedentary lifestyle, pressure sores, results from falls, bowel obstruction, dependence on assistive devices and its economic impact, lack of access to medical care, and social isolation.

2. *Personal Care/Home Management* refers to an individual's ability to perform basic self-care activities such as feeding, bladder and bowel care, personal hygiene, dressing, financial management, and homemaking. Examples of underlying conditions or diagnoses include asthma, arthritis, stroke, osteoporosis, paraplegia, or multiple sclerosis. Secondary conditions may include lack of physical fitness, incontinence, weight gain, poor nutrition, and emotional dependence.

3. *Communication* refers to an individual's ability to generate and express messages, and to receive and understand messages. Examples of underlying conditions or diagnoses include cerebral palsy, deafness, aphasia from varied pathology, or congenital speech impediments. Secondary conditions may include family dysfunction, isolation, and constraints and barriers in employment opportunity.

4. *Learning* refers to an individual's ability to profit from daily experiences,

and includes aspects of receiving, processing, remembering, and using information. Examples of underlying conditions or diagnoses include mental retardation, spina bifida, fetal alcohol syndrome, or traumatic brain injury. Secondary conditions may include depression, behavioral problems, increased family stress, and poor academic and vocational performance.

Note that the examples listed above are illustrative, and not intended to be exhaustive; several secondary conditions may apply to more than one disability domain. Because of limited funds and other resources available, this Announcement does not include disabilities created by psychiatric diagnoses, although mental health issues may be appropriately included as secondary conditions.

The model of health promotion used for Part 1 of this Announcement assumes a goal of promoting health and preventing secondary conditions among persons with disabilities. The basic conceptual model is represented by the International Classification of Impairments, Disabilities, and Handicaps (ICIDH). Revisions proposed to the ICIDH framework include definitions and concepts consistent with a broader perspective of the disabling process. Of particular importance is the utility of this paradigm for data collection, given its classification of disabilities and related variables. Definitions referenced in this framework are presented below:

1. *Participation* refers to the product of the interactions between the individual and the environment, and is delineated by the outcomes of that interaction. The intent of this dimension is to document the nature and extent of a person's involvement in life activities. This dimension is broadly analogous to the term ''Handicap'' in the ICIDH (World Health Organization, 1980) model and the term ''Disability'' in the Institute of Medicine (IOM, 1991) model.

2. *Environment* refers to the physical, social, and cultural contexts in which the individual acts. Elements of the environment create the backdrop for the individual's participation, as facilitators or hindrances.

3. *Impairment* refers to loss or abnormality in a body structure, organ, or system as a consequence of disease, injury, or congenital disorder. In the context of health experience, an impairment is any loss or abnormality of psychological, physiological, or anatomical structure or function.

4. *Disability* refers to any restriction or lack of ability to carry out simple or complex activities of everyday life. It is the manifestation of an underlying impairment, but may vary by age or developmental stage.

5. *Health Promotion* is the effort to educate persons with a disability about the relationship between protective and risk factors and secondary conditions, and to increase behaviors consistent with a healthy lifestyle. Health promotion concerns those behaviors that affect health status and are under the direct control of persons who have a disability.

6. *Secondary Conditions* are those physical, medical, cognitive, emotional, or psychosocial conditions, (to which persons with a disability are more vulnerable by virtue of an underlying condition), including adverse outcomes in health, wellness, participation, and quality of life.

7. *Protective Factors* are biological, environmental (social and physical), and lifestyle or behavioral characteristics that reduce or mitigate the risk for adverse health outcomes, enhance coping skills, induce a positive mediating influence against the effects of secondary conditions, and/or promote health.

8. *Risk Factors* are biological, environmental (social and physical), and lifestyle or behavioral characteristics that increase the risk for adverse health outcomes. Identifying such factors can contribute to determining a course of action during the disabling process, including the development of preventive interventions.

9. *Quality of Life* is associated with the concept of well-being, encompassing both physical and psychosocial determinants. Components of quality of life include performance of social roles, physical status, emotional status, social interactions, economic status, and self-perceived or subjective health status.

Background for Part 2

Pressure sores are the most common and costly complication among persons with spinal cord injury. There are an estimated 200,000 persons with spinal cord injury in the United States. Almost all persons with spinal cord injury will experience at least one pressure sore in their lifetime. Although estimates vary, the prevalence of pressure sores may be more than 20 percent among persons with spinal cord injury. One study showed that the average institutional costs (for acute care and rehabilitation hospitalizations) for pressure sores were $92,723. The overall cost of hospital stays and economic loss due to pressure sores may be over $6 billion each year (regardless of underlying condition).

Pressure sores are lesions caused by unrelieved pressure, trauma, friction, and/or moisture which damages the skin and then the underlying tissues. Much is known about the factors associated with pressure sore development and treating pressure sores once they occur. Pressure sores are also considered the secondary condition most amenable to prevention among persons with spinal cord injury. As part of rehabilitation, persons with spinal cord injury are taught how to care for their skin and how to prevent pressure sores once they leave the hospital environment and return home. Despite this training, persons with spinal cord injury continue to experience pressure sores.

Despite what is known about the factors associated with the development of pressure sores, little is known about why persons with spinal cord injury do not optimize skin care and other behaviors to prevent pressure sores from occurring. One study, conducted by the Arkansas State Spinal Cord Commission, found initial success with an in-home education program in which the incidence of pressure sores decreased by 19 percent. In long-term follow-up, however, the incidence of pressure sores actually increased among program participants.

Because few such programs have been developed and implemented, little is known about community-based prevention programs for the prevention of pressure sores. The emphasis here is prevention and early intervention rather than treatment. Recognizing that individual situations vary, assessment of risk for developing pressure sores and education for prevention should be done in the context of individual needs, strengths, and environment. Applicants should use available information on pressure sore prevention in the post-rehabilitation, community setting to develop a model program and plan, and implement and evaluate the feasibility of doing a home-visitation program.

Program Requirements for Part 1

Applicants must design, develop, and evaluate health promotion programs or conduct an epidemiologic study that will contribute to a national information base for the prevention of secondary conditions. CDC has indicated the following four areas for emphasis under Part 1 of this Announcement and applicants must develop their proposals to respond to one of these four areas.

1. Development of reliable and valid measurements to assess Participation among persons with disabilities, and characteristics of the Environment which influence that participation.

Applicants may choose to work across disability domains. These are evolving dimensions to the ICIDH framework to replace the ''Handicap'' dimension. There is a pressing need to clarify and understand these dimensions and characteristics. There is a benefit in having the capacity to assess empirically the influence of environment on participation in life activities for persons with disabilities. The need to assess these dimensions to improve the health status, expand research emphasis, and develop policy regarding persons with disabilities is both timely and critical.

2. Work toward measuring the cost-effectiveness of one or more intervention strategy(ies) designed to minimize the effects of or prevent selected secondary condition(s). In order to guide the conduct of cost-utility and cost-effectiveness analysis in federally funded programs, the PHS recently developed consensus-based Cost-Effectiveness Recommendations which have direct applicability to research on the prevalence and consequences of secondary conditions. Applying cost-utility and/or cost-effectiveness analytic techniques improves the basis for the allocation of health care resources across a broad range of secondary conditions among many preventive, therapeutic, rehabilitative, and public health interventions. The PHS Cost-Effectiveness Recommendations emphasize standardization of methods, adoption of the societal perspective in conducting analyses, and use of the summary measure known as the ''quality-adjusted life year'' (QALY) as a comparable metric for recording the effects of different interventions. Thus, there is both an opportunity and a need to establish basic prevention strategies that focus on common secondary conditions, and to apply methods that evaluate their comparative cost-effectiveness, so that successful strategies and approaches can be generalized and replicated in other settings. Reference citations for these published recommendations are presented in the Bibliography, which is an attachment to this Announcement.

3. Identification and measurement of protective factors and risk factors within a disability domain, and measurement of the effectiveness of preventive interventions that focus on an identified age group that includes: (a) Children; (b) youth; and/or (c) older adults. Given the paucity of research on secondary conditions generally, there is even less data available on specific age groups within the population which may be even more susceptible to developing secondary conditions.

4. Identification and measurement of protective factors and risk factors within a disability domain, and measurement of the effectiveness of preventive interventions among specified populations that include women and/or ethnic minority groups, or a combination of the two. Among persons with disabilities, susceptibility to secondary conditions may be higher in particular populations. Emphasis should be given to populations considered to be at greatest risk.

Program Requirements for Part 2

Applicants must develop proposals to address pressure sores and other selected secondary conditions among persons with spinal cord injury. The model program proposed should be home-based and able to collect information on and address medical, social, and environmental factors associated with the development and progression of pressure sores and other selected secondary conditions.

Applicants should address the development, implementation, and appropriate evaluation of a home-based model project to prevent pressure sores and other selected secondary conditions among persons with spinal cord injury. The emphasis of the project should be to assess the feasibility of the program, including access to persons with spinal cord injury, recruiting and retaining study participants, logistical management and support of a home-based visitation program, and educational materials for the prevention of pressure sores and other selected secondary conditions. Applicants should consider addressing persons with spinal cord injury at greatest risk of secondary conditions, including persons of low socioeconomic status or persons considered medically underserved. A close working relationship between the recipient and CDC is expected.

Applicants for Part 2 should develop a prevention program based on a public health nurse, home-visit model. The project should include the following elements:

1. Collect, compile, and analyze information relevant to the prevention of pressure sores and other selected secondary conditions among persons with spinal cord injury;

2. Develop a program consisting of the following phases:

a. A twelve month planning/recruitment phase where the recipient explores existing materials relevant to the program, identifies and selects other secondary conditions to be addressed, identifies educational materials to be used for the prevention of pressure sores and the other identified secondary conditions, hires and trains home visitation staff, and identifies and recruits study participants.

b. An implementation phase where the home visitation project is implemented (data collection, education) in the target population.

c. A monitoring phase where the intervention project continues with the monitoring of the intervention, the occurrence of pressure sores, the occurrence of other secondary conditions, and associated risk factors.

d. A follow-up phase for continued monitoring and evaluation.

3. Develop and implement the methods (both scientific and operational) for collecting data to assess the impact of the intervention.

4. Determine how data will be maintained including format and databases, and confidentiality protections.

5. Obtain the necessary clearances and agreements to proceed with all aspects of the proposed project, including appropriate human subjects clearances and agreements with other organizations and individuals needed to complete the project. This specifically includes working with CDC to obtain human subjects clearances and approval for data collection activities.

6. Identify or develop, and pilot test data collection instruments.

7. Establish baseline rates for pressure sores or other secondary conditions within the target group. Identify potential data sources to provide baseline information or data for comparison.

8. Monitor progress toward achievement of project goals through the use of realistic, measurable, time-oriented objectives for all phases of the project.

9. Develop collaborative relationships with voluntary, community-based public and private organizations addressing issues important to persons with spinal cord injury. These could include centers for independent living, and local chapters of the Paralyzed Veterans of America and the National Spinal Cord Injury Association.

Cooperative Agreement Activities (Part 2 Only)

In conducting activities to achieve the purposes of Part 2 of this Announcement, the recipient shall be responsible for activities listed under A. (Recipient Activities), and CDC shall be responsible for activities listed under B. (CDC Activities):

A. *Recipient Activities:*

1. Collect, compile, and analyze information relevant to the prevention of pressure sores and other selected secondary conditions among persons with spinal cord injury.

2. Develop a home-visit prevention model program consistent with the public health nurse approach and framework.

3. Implement the home visitation project (data collection, education) in the target population.

4. Monitor the intervention, the occurrence of pressure sores, the occurrence of other secondary conditions, and associated risk factors.

5. Provide for ongoing project evaluation.

6. Provide for final dissemination of the products of the research including conclusions and recommendations suitable for broad replication in other prevention settings.

B. *CDC Activities:*

1. Provide technical consultation on: existing materials relevant to the program (educational materials to be used for the prevention of pressure sores and the other identified secondary conditions), the selection of other secondary conditions to be targeted, and the identification and recruitment of study participants.

2. Participate in program planning and development.

3. Participate in the development of the evaluation aspects of the project.

4. Provide consultation in the development of data collection instruments, methods, and procedures.

Application Contents—Part 1

1. Describe the applicant organization's current activities that relate to the prevention of secondary conditions. Define the populations included and the scope of any current research, specific health promotion or training interventions, and the outcomes and use made of such interventions and services.

2. Provide the rationale and basis for both the selection of a disability domain(s) and the selected area for emphasis for the proposed research agenda.

3. Discuss how the applicant organization is in an advantageous position to conduct the proposed project, and describe the special competencies residing in the applicant organization for conducting the project.

4. Describe the applicant's experience and prior performance in similar programs that would be beneficial in carrying out the proposed project and outline the function and identity of all collaborating organizations in the proposed project.

5. Describe the existing or proposed linkages and formal collaborations to meet all operational and epidemiologic requirements for achieving the goals and objectives of the research agenda, including timely access to needed data and study populations and clients related to the selected area for emphasis.

6. Present letters and agreements that demonstrate commitment and support and provide tangible evidence of appropriate collaboration.

7. Describe the data to be collected, accessed, or developed to conduct the proposed project, and the methods for collecting data from specified sources. Discuss the strengths and weaknesses of each data source relative to the proposed project. Explain how the standardization and uniformity of data will be addressed to make the information useful to other organizations.

8. Present the design of the study proposal or intervention that includes: (a) Providing case definitions; (b) outlining methods of enrolling and managing cases, clients, or cohorts; (c) describing plans to ascertain cases and estimate sample size or study power; (d) describing study methods and an analytical plan; (e) describing how the confidentiality of cases identified through the project will be protected; and (f) how the research will be evaluated.

9. Present the plan for dissemination of findings and recommendations. Indicate the prospects for replicating the research in the development of interventions that will benefit other populations, including applications for national use.

10. Describe the placement of the project within the applicant organization and outline how it will function to meet the objectives of the grant. Provide an organizational chart illustrating the placement of the project and how it will interact with partner entities.

11. Present the management plan, incorporating methods and time frames for conducting the project including staff selection and appointment, intra/inter-agency agreements, data access negotiations, management oversight, and development of training or health promotion material. Provide curriculum vitae for identified key personnel.

12. Present overall goals and objectives for the entire three year project period, including detailed and specific goals and quarterly objectives with timelines, in a work plan that covers the first two budget years.

13. Present the methods, approach, and designation of responsibilities for evaluation of the management elements of the project over the duration of the grant.

14. Present what will occur to assure that all project activities and facilities will permit full access to minorities, both sexes, and persons with disabilities, and to provide opportunities for persons with disabilities to participate in research operations.

15. Prepare specific budget and cost projections with full narrative justification, for all listed budget class categories, identifying both Federal and non-Federal sources. Indicate the amount and categories of applicant cost-sharing in the total budget. Provide projections and commitments (citing sources of funding) for cost-sharing in both the second and third years of the project period.

16. *Human Subjects:* This section must describe the degree to which human subjects may be at risk and the assurance that the project will be subject to initial and continuing review by the appropriate institutional review committees.

Evaluation Criteria—Part 1 (Total 100 Points)

Under Part 1, applications for Secondary Conditions Research will be reviewed and evaluated for technical merit based on the following factors:

1. Evidence of Understanding: (15 Points)

Evaluation will be based on:

a. The applicant's description of the public health significance of secondary conditions and adherence to the purposes of this Announcement, with an emphasis on the applicant's capacity to reach the populations proposed.

b. The organizational rationale for determining the disability domain(s) for project operations, and for addressing one of the areas for emphasis outlined in the Program Requirements section for Part 1.

2. Research Resources and Organizational Capacity: (20 Points)

Evaluation will be based on:

a. The capability of the applicant to conduct the project, taking into account its institutional experience and current activities in the field proposed for this research.

b. The ability of the applicant to ensure timely access to necessary population-based data related to the selected area for emphasis.

c. The capacity of the applicant to identify and work with selected targeted activities and expeditiously gather required information about the clients or populations under investigation.

d. The applicant's capacity to provide evidence of effective collaborations and research linkages enabling the applicant to meet all protocol development and operational research requirements for the project.

3. Research Approach: (35 Points)

Evaluation will be based on:

a. The extent to which the proposed methods, sources of data, process for identifying individuals and cohorts with disabilities, and/or conducting health promotion programs will be employed and function to address the selected area for emphasis in this Announcement.

b. The overall strength of the research design including: (1) The rationale and appropriateness of the study protocol and methods; (2) the quality and scope of the data collection and data analysis plan; (3) the power of the scientific dimensions in the design, including sample size, measurements, etc; (4) the scope of the plan to assure confidentiality as applicable to the protocol; and (5) the process by which the research will be evaluated, including expected outcomes. For applicants selecting the second area for emphasis pertaining to cost-effectiveness, evaluation of the proposed methods will also be based on adherence to generally accepted techniques for conducting and reporting on cost-utility or cost-effectiveness analyses.

c. The overall information dissemination plan for presenting and publishing the findings and recommendations of the research, and the potential for generalizability and replicability of the study.

4. Management Plan and Project Goals and Objectives: (30 Points)

Evaluation will be based on:

a. The description of the management plan and approach, including the project's location within the applicant organization, and the described process by which the applicant will meet the goals and objectives of the proposed research agenda.

b. The presentation of the specified tasks and responsibilities for all positions proposed for financial assistance, and for other personnel contributing to the requirements of the project.

c. The applicability of the proposed goals and specific objectives related to the conduct of the project, including proposed timelines.

d. The process for overall evaluation of the management of the project, including the assignment of responsibility for ongoing review of specified components.

e. The extent to which the application furnishes evidence that project activities will be fully accessible to minorities, both sexes, and persons with disabilities, and will include opportunities for persons with disabilities to participate in project activities.

5. Project Budget: (Not Scored)

This criteria includes the adequacy of the project application budget in relation to program operations, collaborations, and services; the extent of cost-sharing; and the extent to which the budget is reasonable, clearly justified, accurate, and consistent with the purpose of this Announcement.

6. Human Subjects: (Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects.

Application Contents—Part 2

1. Describe the impact of pressure sores and other proposed secondary conditions.

2. Describe the applicant organization's current activities related to the prevention of pressure sores and other secondary conditions among persons with spinal cord injuries. Define the populations included.

3. Describe the target population, the rationale for selection of that population, and whether and why the population is considered undeserved.

4. Discuss how the applicant organization is in an advantageous position to conduct the proposed project, and describe the special competencies residing in the applicant organization for conducting the project.

5. Describe the applicant's prior experience and performance in similar programs that would be beneficial in carrying out the proposed project and outline the function and identity of all collaborating organizations in the proposed project.

6. Describe the existing and proposed linkages and formal collaborations to meet all operational and epidemiologic requirements for achieving the goals and objectives of the project. Letters and agreements that demonstrate commitment and support and provide tangible evidence of collaboration for specific aspects of the proposed research must be included.

7. Present the design of the study proposal or intervention that includes: (a) Providing case definitions; (b) outlining methods of enrolling and managing cases, clients, or cohorts; (c) describing plans to ascertain cases; (d) describing study methods and an analytical plan; (e) describing how the confidentiality of cases identified through the project will be protected; and (f) how the research will be evaluated.

8. Describe the data to be collected, accessed, or developed to conduct the proposed project, and the methods for collecting data from specified sources. Discuss the strengths and weaknesses of each data source to the proposed project.

9. Present the plan for dissemination of findings and recommendations. Indicate the prospects for replicating the research in the development of interventions that will benefit other populations, including applications for national use.

10. Describe the placement of the project within the applicant organization and outline how it will function to meet the objectives of the cooperative agreement. Provide an organizational chart illustrating the placement of the project and how it will interact with partner entities.

11. Describe the management plan, incorporating methods and time frames for conducting the project in operational areas including staff selection and appointment, protocol development, intra/inter-agency agreements, data access negotiations, study population monitoring and tracking systems, data analysis, and development of training or health promotion material. Provide curriculum vitae for identified key personnel.

12. Present overall goals and objectives for the entire three year project period, including detailed and specific goals and quarterly objectives with timelines, in a work plan that covers the first two budget years.

13. Present the plan, methods, approach, and designation of responsibilities for evaluation of the management elements of the project over the duration of the project.

14. Present what will occur to assure that all project activities and facilities will permit full access to persons with disabilities, and to provide opportunities for persons with disabilities to participate in research operations.

15. Prepare specific budget and cost projections with full narrative justification, for all listed budget class categories, identifying both Federal and non-Federal sources. Indicate the amount and categories of applicant cost-sharing in the total budget. Provide projections and commitments (citing sources of funding) for cost-sharing in

both the second and third years of the project period.

16. *Human Subjects:* This section must describe the degree to which human subjects may be at risk and the assurance that the project will be subject to initial and continuing review by the appropriate institutional review committees.

Evaluation Criteria—Part 2 (Total 100 Points)

Under Part 2, applications for the Prevention of Pressure Sores and other Secondary Conditions among Persons with Spinal Cord Injury will be reviewed and evaluated for technical merit based on the following factors:

1. Evidence of Understanding: (15 Points)

Evaluation will be based on:

a. The applicant's description of the public health significance of pressure sores and other secondary conditions (as chosen by the applicant).

b. The rationale for determining the target population of persons with spinal cord injury.

2. Research Resources and Organizational Capacity: (20 Points)

Evaluation will be based on evidence of:

a. The capability of the applicant to conduct the project, taking into account prior history of conducting research and disseminating results in peer-reviewed publications and in presentations.

b. The ability of the applicant to ensure timely access to the population, including prior history of working with the target population.

c. The capacity of the applicant to identify and work with its selected targeted activities and expeditiously gather required information from the program participants and other populations related to the program activities.

d. The applicant's capacity to provide evidence of effective collaborations and research linkages (i.e., letters of commitment) enabling the applicant to meet all protocol development and operational research requirements for the project.

3. Research Approach: (35 Points)

Evaluation will be based on:

a. The extent to which the proposed methods, sources of data, process for identifying individuals and cohorts with spinal cord injuries will be employed to address the Program Requirements section for Part 2.

b. The overall strength of the research design including: (1) The rationale and appropriateness of the study protocol; (2) the quality of the data collection plan; (3) the scope of the plan to assure confidentiality as applicable to the protocol; and (4) the process by which the research will be appropriately evaluated, including expected outcomes.

c. The overall information dissemination plan for presenting and publishing the findings and recommendations of the research, and the potential for generalizability and replicability of the study.

4. Management Plan and Project Goals and Objectives: (30 Points)

Evaluation will be based on:

a. The description of the management plan and approach.

b. The presentation of the specified tasks and responsibilities for all positions proposed for financial assistance, and for other personnel contributing to the requirements of the project.

c. The applicability of the proposed goals and specific objectives related to the conduct of the project, including proposed timelines.

d. The proposed process for overall evaluation of the management of the project, including the assignment of responsibility for ongoing review of specified components.

e. The extent to which the application furnishes evidence that project activities will be fully accessible to persons with disabilities, and will include opportunities for persons with disabilities to participate in project activities.

5. Project Budget: (Not Scored)

This criteria includes the adequacy of the project budget in relation to program operations, collaborations, and services; the extent of cost-sharing; and the extent to which the budget is reasonable, clearly justified, accurate, and consistent with the purpose of this Announcement.

6. Human Subjects: (Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects.

Reporting Requirements

Narrative progress reports will be required twice annually; and will be due 30 days after the close of each six-month period based on the starting date of the project. An original and four copies of the narrative progress report should be submitted to the CDC Grants Management Branch at dates to be specified in the Notice of Grant Award. An original and two copies of the Financial Status Report is required no later than 90 days after the end of each budget period.

Funding Priorities

Under Part 1, four areas are listed for emphasis within the Program Requirements section. To the extent that there are a sufficient number of high-ranking applications, CDC plans to make awards in all four areas of emphasis. Part 1 applications will be reviewed by an internal CDC review panel.

Under Part 2, CDC plans to fund one project to address pressure sore prevention among persons with spinal cord injury. Part 2 applications will be reviewed by a Special Emphasis Panel (SEP) with knowledge and expertise in pressure sores and/or epidemiology and public health. The SEP may consist of a physiatrist, a physical therapist, an epidemiologist, a program management official, and a person with a disability or family member of a person with a disability.

Special Instructions

Applicants must submit a separate, typed abstract or summary of their proposal consisting of no more than two double-spaced pages as a cover to their application. Applicants should include a table of contents for both the project narrative and attachments. Applicants must denote the component of this Announcement (Part 1 or Part 2) for which they are submitting a proposal. The budget narrative and full budget justification must be placed immediately after the table of contents and abstract for the main application. Applicants should follow the application contents section for the selected component of this Announcement, as those elements are arranged to be compatible with the respective evaluation criteria.

The main body of the application narrative should not exceed 50 double-spaced pages. Pages must be numbered and printed on only one side of the page. All material must be typewritten; with 10 characters per inch type (12 point) on 8–½″ by 11″ white paper with at least 1 margins, headers and footers (except for applicant-produced forms such as organizational charts, graphs and tables, etc.). Applications must be held together only by rubber bands or metal clips, and not bound together in any other way.

Attachments to the application should be held to a minimum in keeping to those items required by this Announcement. Other columns on the Standard Form 424A budget sheet

should be used to define and certify other cost-sharing, with the specific sources identified and documented in the budget narrative.

CDC expects to sponsor annual project workshops for all grantees. By virtue of accepting an award, projects have agreed to use grant or cooperative agreement funds to travel to and participate in these workshops. Applicants should budget travel funds to attend a workshop in Atlanta during the first year.

Executive Order 12372

Applications are not subject to the Intergovernmental Review of Federal Programs as governed by Executive Order 12372.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance (CFDA)

The Catalog of Federal Domestic Assistance number is 93.184.

Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. Applicants will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals, and funded by grants/cooperative agreements will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the ''PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office of Protection from Research Risks at the National Institutes of Health.

Women and Minority Inclusion Policy

It is the policy of CDC to ensure that women and racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive Number 15 and include American Indian, Alaska Native, Asian, Pacific Islander, Black, and Hispanic. Applicants shall ensure that women, racial, and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol.60, No. 179, Friday, September 15, 1995, pages 47947–47951.

Application Submission and Deadline

A. Pre-Application Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent to apply is requested from potential applicants. The letter should be submitted to the Grants Management Officer whose name is noted in section B below. The letter should be postmarked no later than 30 days prior to the submission deadline. The letter of intent should identify the Announcement Number; name the proposed project director; and in a paragraph, describe the scope of the proposed project. The letter will not influence review or funding decisions, but it will enable CDC to plan the review more efficiently and ensure that each applicant receives timely and relevant information prior to application submission.

B. Application Submission

Applicants should submit an original and four copies of the application (PHS Form 398—OMB Number 0925–0001 revised 5/95), and adhere to the ERRATA Instruction Sheet contained in the Grant Application Kit. Applications must be submitted to Mr. Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, Georgia 30305, on or before Thursday, May 15, 1997.

1. *Deadline:* Applications will be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U. S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U. S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.a. or 1.b. above are considered late. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked your name, address, and telephone number and will need to refer to Announcement Number 731. You will receive a complete program description, information on application procedures, and application forms. In addition, this Announcement and the bibliography attachment for Part 1 is also available through the CDC Home Page on the Internet. The address for the CDC Home Page is http://www.cdc.gov. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Georgia L. Jang, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), East Paces Ferry Road, NE., Room 321, Mailstop E–13, Atlanta, Georgia 30305, telephone number (404) 842–6814. (Internet address: glj2@cdc.gov).

For Part 1 applications, program assistance may be obtained from Joseph

B. Smith, Office on Disability and Health, National Center for Environmental Health, CDC, 4770 Buford Highway, Building 101, Mailstop F–29, Atlanta, Georgia 30341, telephone (770) 488–7082. (Internet address: jos4@cdc.gov). Epidemiologic and research-related technical assistance is available from Donald J. Lollar, Ed.D. at the same address, telephone (770) 488–7094. (Internet address: dcl5@cdc.gov).

For Part 2 applications, program assistance may be obtained from Douglas R. Browne, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, Building 101, Mailstop F–41, Atlanta, Georgia 30341, telephone (770) 488–4031. Internet address: drb7@cdc.gov. Epidemiologic and research-related technical assistance is available from Joe Sniezek, M.D., M.P.H. at the same address and telephone number. Internet address: jes6@cdc.gov. A packet of background information for Part 2 is available by contacting the above listed CDC staff.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report; Stock number 017–001–00474–0) or ''Healthy People 2000'' (Summary Report; Stock number 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: March 7, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–6489 Filed 3–13–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 97N–0036]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information regarding the Cosmetic Product Voluntary Reporting Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. This document announces the OMB approval number.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 23, 1996 (61 FR 67556), the agency announced that the proposed information collection had been submitted to OMB for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB has approved the information collection and assigned OMB control number 0910–0030. The approval expires on January 31, 2000. Under 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

Dated: March 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6524 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0497]

I. D. Russell Co. Laboratories; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by I. D. Russell Co. Laboratories. The NADA provides for use of 10 percent sulfaquinoxaline powder for making animal feed and 20 percent sulfaquinoxaline liquid. The sponsor requested the withdrawal of approval because the products are no longer being marketed.

EFFECTIVE DATE: March 24, 1997.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: I. D. Russell Co. Laboratories, 1301 Iowa Ave., Longmont, CO 80501, is the sponsor of NADA 6–776, which provides for use of 10 percent sulfaquinoxaline powder for feed and 20 percent sulfaquinoxaline liquid. I. D. Russell Co. Laboratories requested that FDA withdraw approval of NADA 6–776 because the products are no longer being marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 6–776 and all supplements and amendments thereto is hereby withdrawn, effective March 24, 1997.

Dated: February 3, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–6474 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 95P–0061, 95S–0117, 95S–0126, and 95S–0135]

Expiration Dates for Patents Extended by the Uruguay Round Agreements Act; Submission by Applicants of New Drug and New Animal Drug Applications; Withdrawal of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a notice published in the Federal Register of July 21, 1995 (60 FR 37652), which announced the agency's position on patent information submitted by applicants of new drug applications (NDA's) and new animal drug applications (NADA's). On April 4, 1996, the U.S. Court of Appeals for the Federal Circuit issued a decision establishing the correct method for calculating patent term expiration dates for certain patents that are subject to both the Uruguay Round Agreements Act (URAA) and the patent term extension provisions of the U.S. Code. All NDA and NADA applicants should calculate patent term expiration dates in conformance with the court's decision and submit corrected patent term expiration dates to the agency.

DATES: NDA and NADA applicants that have already submitted patent term expiration dates should submit patent term expiration dates calculated in accordance with this notice by April 14, 1997.

ADDRESSES: Two copies of amended patent information pertaining to human drug products regulated under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) by the Center for Drug Evaluation and Research (CDER) should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by the Center for Biologics