ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology. The template may be found on the ACL Web site at *http://www.acl.gov/NewsRoom/NewsInfo/docs/FFR-ACL-AoA-TitleIII-Supplemental_SF-425.pdf.*

The supplemental form to the Financial Status Report for all ACL/AoA Title III Grantees provides an understanding of how projects funded by the Older Americans Act are being administered by grantees, in conformance with legislative requirements, pertinent Federal regulations and other applicable instructions and guidelines issued by the Administration for Community Living (ACL). This information will be used for Federal oversight of Title III projects. ACL estimates the burden of this collection of information as follows: 56 State Units on Aging (SUA) respond semi-annually which should have an average burden of 2 hours per grantee for a total of 112 hours per submission.

Dated: April 8, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–08200 Filed 4–10–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Paralysis Resource Center

Summary: The Administration for Community Living (ACL) is proud to announce the Paralysis Resource Center (PRC) is moving to ACL as a result of the 2014 budget recently signed by President Obama.

ACL was formed in April 2012 to advance policy and implement programs that support the rights of older Americans and people with disabilities to live in their communities throughout their lifespan. The mission of the PRC aligns perfectly with ACL's mission and provides the Administration with important new programmatic opportunities to help persons with physical disabilities as well as older adults and people with developmental disabilities.

The PRC provides a comprehensive, national source of information for people living with paralysis and their families to promote health, foster involvement in the community, and improve quality of life. Resources on spinal cord injury, paralysis and mobility-related disabilities, including information and referral by phone and email are available in English and Spanish. The PRC currently operates through a cooperative agreement between the Christopher & Dana Reeve Foundation and the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC). ACL will be working with the CDC on transitioning the program to ACL.

Program Name: Paralysis Resource Center.

Award Amount: Up to $6,683,000.

Project Period: 6/1/2014 to 5/31/2015.

Award Type: Cooperative Agreement.

Statutory Authority: This program is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241, 247b(k)(2)).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.325 Discretionary Projects.

Dates:

- *Application Submission deadline:* May 12, 2014.
- The anticipated budget period start date is June 1, 2014.

I. Program Description

The purpose of the program is to provide funding to support a national Paralysis Resource Center to improve the health and quality of life of individuals living with paralysis and their families by raising awareness of and facilitating access to a broad range of services relevant to individuals with paralysis. The Paralysis Resource Center will work to remove environmental barriers to health for individuals living with paralysis and expand the knowledge base of proven, successful health promotion strategies leading to improved physical and emotional health for this population, improving the understanding of the true burden of paralysis by disease category, injury, and quality of life indicators and to measure secondary complications, and conducting evaluation projects to translate clinical rehabilitation treadmill therapy to community-based settings and training health care professionals to deliver this intervention. This program addresses the ''Healthy People 2020'' focus area(s): Access to Health Services; Adolescent Health; Disability and Health; Early and Middle Childhood; Educational and Community-Based Programs; Health Communication and Health IT; Healthcare-Associated Infections; Nutrition and Weight Status; Older Adults; Physical Activity and Fitness; Quality of Life and Well-Being; Social Determinants of Health; and Tobacco Use.

Justification for the Exception to Competition

The PRC currently operates through a cooperative agreement between the Christopher & Dana Reeve Foundation and the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC). To ensure uninterrupted continuation of the grant goals and objectives and given the administrative burden of holding an open competition and awarding a new grant given the short time since the funds were appropriated, ACL will award a one year continuation to the incumbent Paralysis Resource Center at the Christopher & Dana Reeve Foundation. Failure to move forward with this deviation would disrupt ACL's ability to improve and advance the PRC program as one cohesive and consistent program nationally.

- *Eligible Applicants:* Incumbent Paralysis Resource Center with award expiration date of 5/31/14.

II. Evaluation Criteria

Information previously provided in semi-annual reports, as well as information in the non-competing extension application will be considered to determine satisfactory progress of the grantee project and ensure that proposed activities are within the approved scope and budget of the grant. Areas that will be evaluated include:

A. *Project Relevance & Current Need.*
B. *Approach.*
C. *Budget.*
D. *Project Impact.*
E. *Organizational Capacity.*

III. Application and Submission Requirements

A. SF 424—Application for Federal Assistance.
B. SF 424A—Budget Information.
C. Separate Budget Narrative/Justification.
D. SF 424B—Assurances. **Note:** Be sure to complete this form according to instructions.
E. Lobbying Certification.
F. Program narrative—no more than 10 pages.

- The project narrative must be submitted to GrantSolutions. The narrative must be submitted in the following format:
- Maximum number of pages: 10—If the narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced; Times New Roman is preferred.

- Double spaced.
- Page margin size: One inch.
- Number all narrative pages; not to exceed the maximum number of pages.
- Include a table of contents.
- Application should be submitted through Grantsolutions at *www.grantsolutions.gov*.

The narrative should address activities to be conducted over the entire project period and must include the following items in the order listed:

i. Plan.

ii. Methods.

iii. Objectives.

iv. Timeline.

v. Staff.

vi. Understanding.

vii. Need.

viii. Evaluation and Performance Measures.

The budget and budget justification will be included as a separate attachment, not to be counted in the narrative page limit. Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitae, Resumes, Organizational Charts, and Letters of Support. Additional information submitted via GrantSolutions.gov should be uploaded in a PDF file format, and should be named as appropriate, such as publications, reports, etc.
- No more than 15 attachments should be uploaded per application.

G. Work Plan.

H. Grantees will be required to access the non-competing application kit in GrantSolutions.gov to submit all materials for this application.

IV. Application Review Information

Applications will be objectively reviewed by Federal staff utilizing the evaluation criteria listed above in Section II.

V. Agency Contact

For further information or comments regarding this program expansion supplement, contact Ophelia M. McLain, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Innovation, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 690–7025; fax (202) 357–3560; email *Ophelia.McLain@acl.hhs.gov*.

Dated: April 8, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–1515]

Determination That ZOVIRAX (Acyclovir Sodium) Injection, Equivalent to 250 Milligrams Base/Vial, 500 Milligrams Base/Vial, and 1 Gram Base/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ZOVIRAX (acyclovir sodium) Injection, equivalent to (EQ) 250 milligrams (mg) base/vial, 500 mg base/vial, and 1gram (g) base/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1 g base/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, is the subject of NDA 18–603, held by GlaxoSmithKline and initially approved on October 22, 1982. ZOVIRAX (acyclovir sodium) is indicated for the treatment of herpes and varicella-zoster (shingles) in immunocompromised patients.

In a letter dated June 20, 2005, GlaxoSmithKline notified FDA that ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated November 15, 2013 (Docket No. FDA–2013–P–1515), under 21 CFR 10.30, requesting that the Agency determine whether ZOVIRAX (acyclovir sodium) Injection, EQ 1 g base/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 250 mg and 500 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, was