DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcing the Intent To Award a Sole-Source Supplement for the Christopher and Dana Reeve Foundation

ACTION: Notice of Intent to award a sole source supplement to the Christopher and Dana Reeve Foundation.

SUMMARY: The Administration for Community Living (ACL) is announcing the award of a sole-source supplement for the National Paralysis Resource Center (PRC) as a result of the 2022 Congressional budget appropriations. The National Paralysis Resource Center is operated by the Christopher and Dana Reeve Foundation and offers important programmatic opportunities for persons with disabilities and older adults. The NPRC provides comprehensive information for people living with spinal cord injury, paralysis, and mobility-related disabilities and their families. Resources include information and referral by phone and email in multiple languages; a peer and family support mentoring program; a military and veterans' program; multicultural outreach services; multiple quality of life grants; and a national website. The administrative supplement for FY 2022 will be in the amount of $747,037, bringing the total award for FY 2022 to $9,447,037.

SUPPLEMENTARY INFORMATION:

Program Name: National Paralysis Resource Center.

Recipient: Christopher and Dana Reeve Foundation.

Period of Performance: The supplement award will be issued for the second year of a five-year project period, July 1, 2022, through June 30, 2023.

Award Amount: $747,037.

Award Type: Cooperative Agreement.

Statutory Authority: This program is authorized under section 317 of the Public Health Service Act (42 U.S.C. 247(b–4)); Consolidated and Further Continuing Appropriations Act, 2016, Public Law 114–113 (Dec. 18, 2015).

CFDA Number: 93.325 Discretionary Projects.

The purpose of the supplemental funding is to support the expansion the 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. With the additional funding, the NPRC will work to expand the National Resource and Information Center; increase the health and quality of life of Americans with disabilities living with paralysis; increase support and resources to people with paralysis, their families and caregivers; expand collaboration with federal agencies and other national organizations that have a vested interested in the paralysis community; and strengthen performance measures.

Dated: August 18, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0447]

Charging for Investigational Drugs Under an Investigational New Drug Application: Questions and Answers; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Charging for Investigational Drugs Under an IND: Questions and Answers.'' Since issuance of the final guidance in 2016, FDA has received questions from stakeholders through the docket and in the form of communications with review divisions. These questions relate to the implementation of FDA's regulation on charging for investigational drugs under an investigational new drug application (IND) for the purpose of either clinical trials or expanded access for treatment use. FDA is providing this revised draft guidance in a question-and-answer format, addressing the most recently asked questions. When finalized, this revised draft guidance will replace the final guidance of the same title issued in June 2016.

DATES: Submit either electronic or written comments on the draft guidance by October 24, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–0447 for ''Charging for Investigational Drugs Under an IND: Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states