

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 interest 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

“THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993-0002, 240-402-8926; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled “Charging for Investigational Drugs Under an IND: Questions and Answers.” When finalized, the revised draft guidance will replace the guidance for industry of the same title issued in June 2016. FDA’s regulation on charging for investigational drugs under an IND for the purpose of either clinical trials or expanded access for treatment use (21 CFR 312.8) allows sponsors to charge for investigational drugs under certain circumstances. FDA issued a guidance in 2016 in a question-and-answer format to respond to the most frequently asked questions concerning various provisions of the regulation.

This revised draft guidance includes responses to stakeholder questions received since publication of the final guidance in 2016. In addition to editorial changes for clarity, significant changes from the 2016 version of the guidance include additional recommendations related to (1) submission of a copy of the receipt or invoice from the manufacturer as documentation when the expanded access sponsor intends to charge only the amount the manufacturer charged for the investigational drug and (2) distribution of the manufacturing, administrative, or monitoring costs from the first year over the expected duration of the expanded IND or protocol.

This revised draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Charging for Investigational Drugs Under an IND: Questions and Answers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have

been approved under OMB control number 0910-0014.

III. Electronic Access

Persons with access to the internet may obtain the revised draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1777]

Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on November 2, 2022, from 9 a.m. to 3:30 p.m. Eastern Time and November 3, 2022, from 9 a.m. to 3:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2022-N-1777.