FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Donna Bethge, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Nutrition and Health Promotion Programs, 202–795–7659, *donna.bethge@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this supplement is to:

- support the development of a survey of key stakeholders to determine falls prevention gaps, opportunities, and priorities in the aging network and expand the Falls Summit to capture strategies and action steps to address those gaps with nationally recognized experts in falls prevention, organizations from the health, nutrition, and aging sectors, select federal and state agencies, professional associations, corporations, and foundations that have an interest in healthy aging;
- expand upon the reach of the Falls Prevention Awareness Week to incorporate additional messaging regarding healthy aging, independence and quality of life that can be realized by moving from falls prevention awareness to action. This will include crafting new messages that will be disseminated to a broader audience to better resonate with older adults and their caregivers;
- provide further development of leaders in the falls prevention network through a fellowship program to focus on systems change to reduce falls, falls risk factors, and fall related injuries to ultimately improve the lives of older adults and save health care dollars; and
- cultivate and leverage partnerships with traditional and new partners, such as emergency medical services, paramedicine, transportation, housing, nutrition, and primary care providers to develop clinical and community collaborative best-practice frameworks and models designed to address multiple risk factors in innovative and scalable ways that would include a strong focus on increasing participation in evidence-based falls prevention programs and embedding those programs into the aging network in order to support healthy and active opportunities for older adults. This supplement would provide the resources necessary to pilot test these frameworks and models in communities.

The administrative supplement for FY 2023 will be in the amount of $2,000,000, bringing the total award for FY 2023 to $3,000,000.

The additional funding will not be used to begin new projects, but it will be used to enhance existing efforts. The grantee will continue to provide appropriate, quality falls prevention resources, increase public awareness about falls prevention and the risk of falls, support the implementation of evidence-based falls prevention programs, and seek new opportunities to embed falls prevention evidence-based programs in the community.

Program Name: National Falls Prevention Resource Center.

Recipient: National Council on Aging (NCOA).

Period of Performance: The supplement award will be issued for the third year of a five-year project period of August 1, 2021, to July 31, 2026.

Total Award Amount: $3,000,000 in FY 2023.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The Older Americans Act, Title IV; and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u–11 (Prevention and Public Health Fund).

Basis for Award

National Council on Aging (NCOA) is currently funded to carry out the objectives of this project through its current cooperative agreement entitled, *National Falls Prevention Resource Center* for the period of August 1, 2021, through July 31, 2026. Since the project's implementation, the grantee has made satisfactory progress toward its approved work plan. The supplement will enable the grantee to carry their work even further, enhancing the support they provide to the Aging Network Falls Prevention Providers. The additional funding will not be used to begin new projects or activities, but rather to enhance efforts.

NCOA is uniquely positioned to complete the work called for under this project. They have an already established infrastructure and are a known and trusted organization in the Aging Network. Prior to this current award, NCOA competed and was twice awarded the *National Falls Prevention Resource Center* for the past 7 years. They have an established presence within the Aging Network. They have a comprehensive, interactive web-based repository (*https://ncoa.org/professionals/health/center-for-healthy-aging/national-falls-prevention-resource-center*) with tools and resources, including—best practices tip sheets, program and fidelity guidance, Falls Prevention Awareness Week toolkit, educational webinars, Grand Rounds recordings, articles covering topics from program implementation through sustainability, resource hubs, policy and practice models, the Falls Free Checkup online screening tool and they maintain the national falls prevention database. Under this current award period, they are providing technical assistance and educational opportunities for the Aging Network's Falls Prevention efforts, including workgroups, webinars, and live trainings. They collaborate nationally with state falls prevention collaboratives and host the annual Age + Action Conference, a grantee gathering to explore solutions to ensure equitable aging for all, connecting with colleagues, sharing innovative ideas, and discussing policy solutions that can be achieved together on behalf of older adults. They have reached thousands of providers using their comprehensive database of SUAs, AAAs, and other Falls Prevention Program stakeholders. In addition, they have developed partnerships with organizations, universities, and other entities to provide technical assistance, education, and support for the Aging Network.

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, it could cause confusion among the Aging Network Falls Prevention Program Providers and stakeholders, which could have a negative effect on training, implementation, and support opportunities. If this supplement were not provided, the project would be unable to address the significant unmet needs of the Aging Network Falls Prevention Program.

Dated: April 18, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–08546 Filed 4–21–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug

Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that JOENJA (leniolisib), approved March 24, 2023, and manufactured by Pharming Technologies B.V., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that JOENJA (leniolisib), manufactured by Pharming Technologies B.V., meets the criteria for a priority review voucher.

JOENJA (leniolisib) is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age or older.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about JOENJA (leniolisib), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08518 Filed 4–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1259]

Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), in cosponsorship with the Duke-Margolis Center for Health Policy, is announcing a public workshop entitled ''Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches.'' This workshop will address innovative manufacturing technologies for drug and biological products and will include a discussion of potential best practices, case studies from previous submissions, potential barriers to adoption, corresponding regulatory strategies, and the Advanced Manufacturing Technologies Designation Program.

DATES: The public workshop will be held on June 8, 2023, from 9 a.m. to 4:30 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by July 8, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the National Press Club, 529 14th Street NW, Washington, DC 20045.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on July 8, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2023–N–1259 for ''Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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