purpose of this project is to improve the quality of life for people with intellectual and/or developmental disabilities (I/DD), brain injuries, and co-occurring mental health conditions by supporting state agencies with policy development, service design, and service coordination resources, and sharing resources to individuals, families, direct support professionals, clinicians, and other policymakers. The administrative supplement for FY 2024 will amount to $410,318 bringing the total award for FY 2024 to $1,060,000.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Dana Fink, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, (202) 795–7604 or via email *dana.fink@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: This supplementary funding will expand the Co-Occurring Resource Center for Individuals with ID/DD (The Link Center)'s engagement and technical assistance efforts around supporting people with co-occurring I/DD, brain injuries, and co-occurring mental health conditions to live well in the community. Additionally, this supplement includes funding from SAMHSA through an interagency agreement to perform an environmental assessment of cross-system strategies to support children with I/DD, brain injuries, and other neurodevelopmental disabilities who also have complex behavioral health conditions. As a result of funding this center and the environmental assessment, ACL expects:

- Improved coordination between mental health, DD, Medicaid, and child welfare service systems to develop and/or amend policies and practices that fill service gaps, recruit and train competent staff, and assure equitable access to quality services.
- Increased number of mental health professionals and paraprofessionals, including community-based mobile crisis intervention service personnel, peer support workers, and service providers for the 988 Dialing Code for the National Suicide Prevention Lifeline, with the competencies needed to provide effective and culturally competent supports to individuals with co-occurring I/DD and mental health disabilities.
- Increased number of community service providers, who have the capacity to support children and adults with I/DD and co-occurring mental health disabilities.
- Improved awareness and knowledge of the strengths, needs, challenges, and systemic barriers experienced by children and adults with co-occurring I/DD and mental health disabilities.
- Improved ability to deliver responsive and equitable programming, training, and technical assistance.
- Increased self-determination, empowerment, and quality of life for people with co-occurring I/DD and mental health disabilities.
- Enhanced service delivery infrastructure, including mechanisms for ongoing and sustained engagement of individuals with lived experience.

This supplement will fund:

- Enhanced efforts related to children and families, including development of relationships with key national child welfare organizations.
- 10 focus groups of cross-system leaders in 10 states on system gaps resulting in adverse impacts on children with complex behavioral health needs.
- An in-person summit with federal and state officials and subject matter experts to discuss findings from the environmental assessment of promising practices and gaps related to children with complex behavioral health needs.
- Increased staff time for coordination, resource development, and accessibility efforts.
- Increased contributions from brain injury partners to align with that of other key partners more closely and better reflect the need to serve people with brain injury as well as I/DD.
- Resource development including paid participation of experts with lived experience to assist in development.
- Additional accessibility and language translation services.

Program Name: Co-Occurring Resource Center for Individuals with I/DD (The Link Center).

Recipient: The National Association of State Directors of Developmental Disabilities Services.

Period of Performance: The supplement award will be issued for the third year of the five-year project period of September 1, 2024, through August 31, 2025.

Total Supplement Award Amount: $410,318.

Award Type: Cooperative Agreement.

Statutory Authority: This program is authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 Public Law 106–402, Section 161(2) (B), (C) and (D) (42 U.S.C. 15081(2)).

Basis for Award: The National Association of State Directors of Developmental Disabilities Services is currently funded to carry out this cooperative agreement for the period of September 1, 2022, through August 31, 2027. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the Link Center project and the beneficiaries being served for ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner.

Dated: September 21, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–22037 Filed 9–25–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0434, FDA–2024–E–0436, and FDA–2024–E–0437]

Determination of Regulatory Review Period for Purposes of Patent Extension; OGSIVEO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for OGSIVEO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by November 25, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 25, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: 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 at the end of November 25, 2024. 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 Nos. FDA–2024–E–0434, FDA–2024–E–0436, and FDA–2024–E–0437 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; OGSIVEO.'' 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 *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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, OGSIVEO (nirogacestat hydrobromide) indicated for adult patients with progressing desmoid tumors who require systemic treatment. Subsequent to this approval, the USPTO received patent term restoration applications for OGSIVEO (U.S. Patent Nos. 7,342,118; 7,795,447; and 7,951,958) from SpringWorks Therapeutics Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 17, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OGSIVEO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OGSIVEO is 5,425 days. Of this time, 5,089 days occurred during the testing phase of the regulatory review period, while 336 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* January 21, 2009. FDA has verified the applicant's

claim that the date the investigational new drug application became effective was on January 21, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 27, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for OGSIVEO (NDA 217677) was initially submitted on December 27, 2022.

3. *The date the application was approved:* November 27, 2023. FDA has verified the applicant's claim that NDA 217677 was approved on November 27, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22105 Filed 9–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Awards Unsolicited Proposal; Catalog of Federal Domestic Assistance (CFDA) Number: 93.079

AGENCY: Office of Population Affairs (OPA) and Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of award of an unsolicited request for funding to be awarded as a single project through a grant to Stanford University, Palo Alto, CA.

SUMMARY: OPA announces the award of a single-source grant in response to an unsolicited proposal from Stanford University, Palo Alto, CA. The proposal submitted was not solicited either formally or informally by any federal government official. The grant award is administered by OPA in collaboration with the Centers for Disease Control and Prevention's Division of Adolescent and School Health (CDC DASH).

DATES: September 13, 2024.

FOR FURTHER INFORMATION CONTACT: Amy Margolis, Deputy Director, Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services at *amy.margolis@hhs.gov* or by telephone at 240–453–2820.

SUPPLEMENTARY INFORMATION:

Recipient: Stanford University, Palo Alto, CA.

Purpose of the Award: The purpose of this award is to conduct and disseminate policy research aligned with the eight goals of HHS's *Take Action for Adolescence: A Call to Action for Adolescent Health and Well-being* to understand the impact of national, state, and local policies on meeting adolescents' needs, and to inform efforts towards strengthening commitments to funding, delivery of services, and meaningful youth engagement.

Amount of Award: $999,855 annually for up to five years.

Project Period: The project period for the award will not exceed five years.

The goals of this project are to conduct and disseminate policy research aligned with *Take Action for Adolescents* to understand the impact of national, state, and local policies on access, availability, and quality of health care and health education for adolescents. Specifically, the project will (1) engage key stakeholders involved in *Take Action for Adolescence,* (2) conduct policy research to identify the impact of national, state, and local policies on access, availability, and quality of health care and health education for adolescents, (3) develop a series of policy briefs that summarize the research and identify strategies to improve adolescent health services and support *Take Action for Adolescents,* and (4) disseminate the policy briefs and effective strategies through publications and focused events with key stakeholders to support sustainability engagements and actions plans to improve adolescent health and well-being. This project will help improve understanding of the impact of national, state, and local policy on education and services for adolescents, and ultimately on their health and well-being.

OPA performed an objective review of the unsolicited proposal from Stanford University with subject matter assistance from within the Department of Health and Human Services and internal proposal assessments. Based on this review, OPA determined that the proposal has merit.

Stanford University, under the leadership of Jonathan Klein, has the unique breadth of expertise in the field of adolescent health and the established partnerships with leading adolescent health organizations necessary for success of this project. Issuing a single-source award to Stanford University for this project will advance our collective understanding of the impact of national, state, and local policies on meeting adolescents' needs and will identify strategies for advancing *Take Action for Adolescents* and improving adolescent health and wellbeing.

This award is being made non-competitively because there is no current, pending, or planned funding opportunity announcement under which this proposal could compete.

Legislative Authority: Funding for this award is provided by CDC DASH with authority under section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a). The grant award will be administered by OPA under an interagency agreement.

Dated: September 17, 2024.

Sarah Rosenthal,

Deputy Assistant Secretary for Population Affairs, Office of Population Affairs, Office of the Assistant Secretary for Health.

[FR Doc. 2024–22029 Filed 9–25–24; 8:45 am]

BILLING CODE 4150–28–P