

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]

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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 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]

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