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, ZTALMY (ganaxolone) indicated for treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in patients 2 years of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for ZTALMY (U.S. Patent No. 8,318,714) from Marinus Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 28, 2023, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZTALMY 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 ZTALMY is 10,382 days. Of this time, 10,065 days occurred during the testing phase of the regulatory review period, while 317 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:* December 30, 1993. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 30, 1993.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 20, 2021. FDA has verified the applicant's claim that the new drug application (NDA) for ZTALMY (NDA 215904) was initially submitted on July 20, 2021.

3. *The date the application was approved or the effective date of approval for a drug product recommended for control under the Controlled Substances Act (21 U.S.C. 811):* June 1, 2022. FDA has verified the applicant's claim that NDA 215904 was approved on March 18, 2022, and that the Drug Enforcement Agency issued an interim final rule controlling the product under section 201(j) of the Controlled Substances Act on June 1, 2022.

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 application for patent extension, this applicant seeks 5 years 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 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20549 Filed 9–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Funding Extension for Rural Behavioral Health Workforce Centers—Northern Border Region

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental funding.

SUMMARY: HRSA will provide a performance period extension with supplemental funds to three fiscal year (FY) 21 award recipients with a period of performance ending on August 31, 2025. The supplemental funding will extend their current period of performance by 12 months to align with the FY 2022 award to an additional recipient, which has a period of performance from September 1, 2022, to August 31, 2025.

FOR FURTHER INFORMATION CONTACT: Jillian Causey, Division Deputy Director, Federal Office of Rural Health Policy, Health Resources and Services Administration, at *jcausey@hrsa.gov* and 301–443–1493.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: Three FY 2021 award recipients: Mary Hitchcock Memorial Hospital—New Hampshire, Medical Care Development, Inc.—Maine, Vermont Association For Mental Health, Inc.—Vermont.

Amount of Non-Competitive Award: Three awards for $1,000,000 each.

Period of Performance: September 1, 2021, to August 31, 2025.

Assistance Listing (CFDA) Number: 93.912.

Award Instrument: Cooperative Agreement.

Authority: Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	State	Award amount
U2SRH43521	Mary Hitchcock Memorial Hospital	NH	$1,000,000
U2SRH43522	Medical Care Development, Inc	ME	1,000,000
U2SRH43523	Vermont Association for Mental Health Inc	VT	1,000,000

Justification: The Northern Border Regional Commission (NBRC) is a federal/state partnership for economic and community development in northern Maine, New Hampshire, Vermont, and New York. NBRC was established by Congress in 2008 to help fund promising economic and community development projects. The states of Maine, New Hampshire, Vermont, and New York play a crucial role in the NBRC region.[1] In FY 2021, HRSA competitively funded three organizations in the NBRC states of Maine, New Hampshire, and Vermont for a period of performance of 3 years. In FY 2022, HRSA competitively funded another organization in the NBRC state of New York for a 3-year period of performance. HRSA is providing a 1-year extension of funding for the FY 2021 awards to align with the FY 2022 award. This would align all awards with a period of performance end date of August 31, 2025.

HRSA is implementing this extension to continue the work of the three recipients because of their benefit to the NBRC region. During their project period, they have increased access to behavioral health and substance use disorder services and strengthened the behavioral health workforce in the NBRC region to improve the health outcomes of NBRC residents.

With program funding, recipients have provided scholarships to mental health rehabilitation technicians to work in rural communities and supported intern work, providing critically needed direct services to the region's neediest, rural residents. Recipients have also funded supervision for several behavioral health clinician positions that serve rural counties, bringing in social workers and postdoctoral psychologist fellows who were able to provide care where there previously had been none. Recipients also have increased access by connecting community members to important resources in their states, including how to find or become a peer recovery coach.

Recipients have also worked to strengthen the behavioral health workforce through training programs such as Project Extension for Community Healthcare Outcomes (Project ECHO, including Medications for Opioid Use Disorder Project ECHO and created the ''Recovery Jobs for Beginners'' program for individuals seeking to work as Peer Recovery Specialists. This program has provided rural communities in the NBRC region with peer recovery specialists where there often are few or none and increased provider skillsets and knowledge. In addition, recipients launched the Mental Health Peer Specialist Certification program within local community colleges in January 2024.

HRSA is implementing project period alignment of the three FY 2021 awards with the FY 2022 award recipient to allow for a seamless continuation of activities and trainings in the region to continue while also allowing all four organizations to identify sustainability strategies over the next fiscal year.

Carole Johnson,

Administrator.

[FR Doc. 2024–20584 Filed 9–10–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Autism Longitudinal Data Project

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA is announcing supplemental award funds through the Patient-Centered Outcomes Research Trust Fund to the current HRSA award recipient to expand activities under the Autism Longitudinal Data Project (ALDP). The funding will be used to create and share a combined de-identified dataset from the Boston Birth Cohort (BBC), Massachusetts Pregnancy to Early Life Longitudinal Data System, and Agency for Healthcare Research and Quality Social Determinants of Health database.

FOR FURTHER INFORMATION CONTACT: Jessica DiBari, Senior Health Scientist, Division of Research, Office of Epidemiology and Research, Maternal and Child Health Bureau, HRSA, at *JDiBari@hrsa.gov* or 301–443–2170.

SUPPLEMENTARY INFORMATION:

(Intended Recipient) of the Award: Johns Hopkins University.

Project Period: The cooperative agreement is currently in year 2 of a 5-year grant cycle. Johns Hopkins University will track the supplemental award from the Patient-Centered Outcomes Research Trust Fund separately from the UT7MC45949 award.

Amount of Award: One award for $457,833.

Assistance Listing (CFDA) Number: 93.877.

Award Instrument: Non-competitive single-source supplement.

Authority: 26 U.S.C. 9511(d)(2)(C).

TABLE 1—AWARD RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	State	Award amount
UT7MC45949	Johns Hopkins University	MD	$457,833

Justification: In fiscal year 2024, the Office of the Secretary's Patient-Centered Outcomes Research Trust Fund, administered by the Office of the Assistant Secretary for Planning and Evaluation, will support a supplement to the HRSA-funded ALDP to create a longitudinal dataset for conducting patient-centered maternal and infant health research by linking multiple databases. Through this supplement, ALDP will develop a dataset on maternal and infant biological, socio-economic, behavioral risk and protective factors, and health services indicators. The ALDP current recipient is uniquely qualified to conduct this work because it has:

- A long-standing record of successfully completing government-funded projects.
- Led and managed the BBC since its inception in 1998.

[1] *https://www.nbrc.gov/content/northern-border-region.*