

Summary of the Award

Recipient: Gambella Regional Health Bureau (GRHB) of Ethiopia.

Purpose of the Award: The purpose of this award is to improve the capacity of HIV program management and quality of health services to attain epidemic control in the Gambella Regional State of Ethiopia.

Amount of Award: The approximate year 1 funding amount will be \$8,000,000 in Federal Fiscal Year (FFY) 2023 funds, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation.

Period of Performance: September 30, 2023 through September 29, 2028.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003).

Dated: March 16, 2023.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–05824 Filed 3–21–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund Public Health Institute of Malawi

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately \$1,000,000, for Year 1 funding to the Public Health Institute of Malawi (PHIM). The award will allow PHIM to efficiently execute Malawi's essential public health functions at national and subnational levels and sustain gains achieved for HIV.

DATES: The period for this award will be September 30, 2023, through September 29, 2028. Funding amounts for years 2–5 will be set at continuation.

FOR FURTHER INFORMATION CONTACT: Nellie Wadonda-Kabondo, Center for Global Health, Centers for Disease Control and Prevention, C/O American Embassy, Box 30016, Lilongwe, Telephone: +265882991033, EMail: vzn7@cdc.gov.

SUPPLEMENTARY INFORMATION: The single-source award will enhance national HIV surveillance and response and strengthen the public health infrastructure and capacity to respond to public health threats and events, including infectious disease outbreaks, pandemics, and other public health emergencies.

The Public Health Institute of Malawi (PHIM) is in a unique position to conduct this work, as The Government of Malawi through the Ministry of Health (MOH) established PHIM in November 2012 with a view to creating a center of excellence on public health that contributes towards quality and productive life of all Malawians.

Summary of the Award

Recipient: Public Health Institute of Malawi (PHIM).

Purpose of the Award: The purpose of this award is for PHIM to efficiently execute Malawi's essential public health functions at national and subnational levels and sustain gains achieved for HIV.

Amount of Award: The approximate year 1 funding amount will be \$1,000,000 in Federal Fiscal Year (FFY) 2023 funds, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation.

Non-PEPFAR Funding: This program is authorized under sections 301(a) and 307 of the Public Health Service Act, as amended [42 U.S.C. 241(a) and 2421].

Period of Performance: September 30, 2023 through September 29, 2028.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003).

Dated: March 16, 2023.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–05823 Filed 3–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of the Assistant Secretary for Children and Families, Administration on Children, Youth and Families; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS

ACTION: Notice.

SUMMARY: The Administration for Children and Families (ACF) has added

a new office, the Office of Family Violence Prevention and Services, to the Office of the Assistant Secretary for Children and Families and transfers the functions of the Division of Family Violence Prevention and Services to this office. Within the Administration on Children, Youth and Families (ACYF), it renames the Office of Management Services to the Executive Office. Within the Family and Youth Services Bureau (FYSB), it renames the Division for Optimal Adolescent Development to the Division of Positive Youth Development and renames the Division of Evaluation, Data, and Policy to the Division of Data, Performance, and Policy. It also creates an Office of Budget in the Office of the Assistant Secretary for Children and Families.

DATES: This reorganization was approved by the Secretary of Health and Human Services on March 1, 2023, and took effect on March 17, 2023.

FOR FURTHER INFORMATION CONTACT: Shawndell Dawson, Division of Family Violence Prevention and Services, 330 C Street SW, Washington, DC 20201, (202) 205–1476.

SUPPLEMENTARY INFORMATION: This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) as follows: Chapter KA, Office of the Assistant Secretary for Children and Families, as last amended by 85 FR 52607, March 26, 2020, and Chapter KB, Administration on Children, Youth and Families (ACYF), as last amended in 85 FR 15785, March 19, 2020. The changes are as follows:

I. Under Chapter KA, Office of the Assistant Secretary for Children and Families, make the following changes:

A. Delete KA.00 Mission in its entirety and replace with the following:

KA.00 Mission. The Office of the Assistant Secretary for Children and Families (OAS) provides executive direction, leadership, and guidance for all ACF programs. OAS provides national leadership to develop and coordinate public and private initiatives for carrying out programs that promote permanency placement planning, family stability, and self-sufficiency. OAS advises the Secretary on issues affecting America's children and families, including Native Americans, refugees, survivors of domestic violence, youth experiencing homelessness, children and families in the child welfare system, and survivors of human trafficking. OAS provides leadership and coordination on human services and early childhood

development issues and conducts emergency preparedness and response operations during a nationally declared emergency.

B. Delete KA.10 Organization in its entirety and replace with the following:

KA.10 Organization. The Office of the Assistant Secretary for Children and Families is headed by the Assistant Secretary for Children and Families who reports directly to the Secretary and consists of:

Office of the Assistant Secretary for Children and Families (KA)
Executive Secretariat Office (KAF)
Office of Human Services Emergency Preparedness and Response (KAG)
Office of the Deputy Assistant Secretary and Inter-Departmental Liaison for Early Childhood Development (KAH)
Office on Trafficking in Persons (KAI)
Office of Family Violence Prevention and Services (KAJ)
Office of Budget (KAK)

C. Establish KA.20 Functions, Paragraph F, The Office of Budget:

F. The Office of Budget manages the formulation and execution of the budgets for OAS programs and OAS' portion of the federal administration budget, serves as the central control point for operational and long range planning, manages procurement planning and provides technical assistance regarding procurement, acquires OAS supplies, provides oversight and technical assistance on funds planning for travel expenditures and travel administration on obligation and payment issues, monitors the obligation and expenditure of OAS funds through the lifecycle of the appropriations, and provides leadership and advice on financial policy issues that cut across all the OAS program and funding mechanisms.

D. Establish KA.20 Functions, Paragraph G, The Office of Family Violence Prevention and Services:

G. The Office of Family Violence Prevention and Services (KAJ):

The Office of Family Violence Prevention and Services (OFVPS) is responsible for the overall leadership of family violence, domestic violence, and dating violence prevention, intervention, response, and awareness programs and services under the purview of ACF. The OFVPS serves as an advisor to the Assistant Secretary, ACF, recommending policy strategies and interagency collaborations to address the coordination of services involving domestic violence survivors and their children. Under the leadership of the Assistant Secretary, ACF, OFVPS assesses policies and legislation, and develops program initiatives for

domestic violence and dating violence prevention and services. OFVPS recommends budgetary and legislative proposals and subject areas for research/evaluation and demonstration activities, and it coordinates efforts with and provides expert advice to departmental and other federal agencies on issues and programs for survivors of domestic violence and their children. The OFVPS promotes public awareness about family violence, domestic violence, and dating violence. The OFVPS also promotes awareness about the impact of family violence, and effective prevention and intervention strategies to address the problem. The OFVPS programs provide immediate shelter and related assistance to survivors of domestic violence, dating violence, and family violence and their dependents; provide for research into the most effective methods of domestic violence prevention, identification, and intervention; and provide training and technical assistance to domestic violence and dating violence programs including states, territories, tribes, coalitions, culturally specific organizations, rural communities, faith-based organizations, local public agencies (such as early childhood programs, social service agencies, child welfare programs, mental health and substance abuse treatment programs, and health care providers), and non-profit organizations. The OFVPS provides support for the National Domestic Violence Hotline, which operates 24 hours a day, 7 days a week and is available in 200 languages, including services in Spanish, video and/or text chat for Deaf and Hard of Hearing survivors, and culturally specific response to Native American victims by Native advocates. The OFVPS supports the development of services to address the needs of children exposed to domestic violence and their abused parents.

The OFVPS is responsible for developing, updating, and implementing program regulations and policies. The OFVPS oversees the receipt and review of applications for formula and discretionary grants and grantee activities. It also provides guidance, review, support, and assistance to states, territories, tribes, coalitions, resource centers, hotlines, and sub awardees on HHS policies, regulations, procedures, and systems necessary to ensure efficient program operation at the state, territorial, tribal, and community levels. In addition, the OFVPS coordinates shelter and supportive service programs for survivors and potential victims of domestic violence, dating violence, and

family violence and their dependents. OFVPS also represents ACF and HHS on various councils, workgroups, and committees and provides leadership and coordination to other ACF and HHS programs and agencies to better meet the needs of domestic violence and dating violence survivors.

II. Under Chapter KB, Administration on Children, Youth and Families, delete KB in its entirety and replace with the following:

KB.00 Mission. The Administration on Children, Youth and Families (ACYF) advises the Secretary, through the Assistant Secretary for Children and Families, on matters relating to the sound development of children, youth, and families by planning, developing, and implementing a broad range of activities that prevent or remediate the effects of trauma, abuse, and/or neglect of children and youth and promote child, adolescent, and family wellbeing.

ACYF administers state grant programs under titles IV–B and IV–E of the Social Security Act, manages the Adoption Opportunities program and other discretionary programs for the development and provision of child welfare services, and implements the Child Abuse Prevention and Treatment Act (CAPTA). It administers programs under the Runaway and Homeless Youth Act and manages prevention programs that support positive adolescent development and wellbeing authorized through Title V of the Social Security Act under Section 510 for Sexual Risk Avoidance Education and Section 513 for Personal Responsibility Education Program.

In concert with other components of ACF, ACYF develops and implements research, demonstration, and evaluation strategies for the discretionary funding of activities designed to improve and enrich the lives of children and youth and to strengthen families. It administers Child Welfare Services training and research and demonstration programs authorized by title IV–B of the Social Security Act and oversees promising youth development programs.

KB.10 Organization. The Administration on Children, Youth and Families is headed by a commissioner, who reports directly to the Assistant Secretary for Children and Families, and consists of:

Office of the Commissioner (KBA)
Executive Office (KBA1)
Office Of Budget (KBA2)
Children's Bureau (KBD)
Children's Bureau Regional Program Units (KBDDI–X)
Office of Child Abuse and Neglect (KBD1)

Division of Policy (KBD2)
 Division of Program Implementation (KBD3)
 Division of Program Innovation (KBD4)
 Division of Child Welfare Capacity Building (KBD5)
 Division of State Systems (KBD6)
 Division of Performance Measurement and Improvement (KBD7)
 Family and Youth Services Bureau (KBE)
 Division of Positive Youth Development (KBE1)
 Division of Data, Performance, and Policy (KBE3)
 Division of Runaway and Homeless Youth (KBE4)

KB.20 Functions. A. The Office of the Commissioner serves as principal advisor to the Assistant Secretary for Children and Families, the Secretary, and other officials of the Department on the sound development of children, youth, and families. It provides executive direction and management strategy to ACYF components. The Deputy Commissioner assists the Commissioner in carrying out the responsibilities of the Office. The Office of the Commissioner is comprised of two offices:

The Executive Office functions as Executive Secretariat for the Office of the Commissioner, including managing correspondence, correspondence systems, and electronic mail requests; coordinates the provision of staff development and training; provides support for ACYF's personnel administration, including staffing, employee and labor relations, performance management, and employee recognition; manages ACYF-controlled space and facilities; performs manpower planning and administration; plans for, distributes, and controls ACYF supplies; provides mail and messenger services; maintains duplicating, fax, and computer and computer peripheral equipment; supports and manages automation within ACYF; provides for health and safety; and oversees travel administration, time and attendance, and other administrative functions for ACYF.

The Office of Budget manages the formulation and execution of the budgets for ACYF programs and for federal administration, serves as the central control point for operational and long range planning, manages procurement planning and provides technical assistance regarding procurement, acquires ACYF supplies, provides oversight and technical assistance on funds planning for travel expenditures and travel administration

on obligation and payment issues, monitors the obligation and expenditure of ACYF funds through the lifecycle of the appropriations, and provides leadership and advice on financial policy issues that cut across all the ACYF program and funding mechanisms.

B. The Children's Bureau (CB) is headed by an Associate Commissioner who advises the Commissioner, ACYF, on matters related to the administration of state and tribal child welfare systems, including child abuse and neglect, child protective services, family preservation and support, adoption, foster care and independent living, and child abuse and neglect prevention. A Deputy Associate Commissioner supports the Associate Commissioner and manages the day-to-day operations of the CB. CB recommends legislative and budgetary proposals, operational planning system objectives and initiatives, and projects and issue areas for evaluation, research, and demonstration activities. CB represents ACYF in initiating and implementing interagency activities and projects affecting children and families, and provides leadership and coordination for the programs, activities, and subordinate components of the Bureau. The Bureau is comprised of eight units:

The Regional Program Unit is headed by the Director of Regional Programs who reports to the Deputy Associate Commissioner, CB, within ACYF. The Director of Regional Programs, through subordinate Regional Program Managers and their staff, in collaboration with program components, is responsible for (1) providing program and technical administration of CB formula, entitlement, block, and discretionary programs related to child welfare, including child abuse and neglect prevention, child protective services, family preservation and support, adoption, foster care, and independent living; (2) collaborating with the ACF Central Office, states, and grantees on all program matters for programs or issues that have significant implications for the programs; (3) providing technical assistance to entities responsible for administering CB programs to resolve identified problems; (4) ensuring that appropriate procedures and practices are adopted; (5) working with appropriate state and local officials to develop and implement outcome-based performance measures; and (6) monitoring the programs to ensure their efficiency and effectiveness, and ensuring that these entities conform to federal laws, regulations, policies, and procedures governing the programs.

The Office on Child Abuse and Neglect provides leadership and direction on the issues of child maltreatment and the prevention of abuse and neglect under CAPTA. It is the focal point for interagency collaborative efforts, national conferences, and special initiatives related to child abuse and neglect, and for coordinating activities related to the prevention of abuse and neglect and the protection of children at risk of maltreatment. It supports activities to build networks of community-based, prevention-focused family resource and support programs through the Community-Based Child Abuse Prevention Grants. It supports improvement in the state systems that handle child abuse and neglect cases, particularly child sexual abuse and exploitation- and maltreatment-related fatalities, and improvement in the investigation and prosecution of these cases through the Children's Justice Act.

The Division of Policy provides leadership and direction in policy development and interpretation of titles IV-B and IV-E of the Social Security Act and the Basic State Grant under CAPTA. It writes regulations and interprets policy for the Bureau's formula and entitlement grant programs and responds to requests for policy clarification from ACF Regional Offices and other sources.

The Division of Program Implementation provides leadership and direction in the operation and review of programs under titles IV-B and IV-E of the Social Security Act and the Basic State Grant under CAPTA. It develops program instructions, information memoranda, and annual reports related to these programs. It analyzes State Plans and develops state profiles and other reports. It is responsible for the Monitoring Team, which schedules and coordinates the monitoring of the state title IV-E reviews and ensures effective corrective action if necessary. It is the focal point for financial issues, including disallowances, appeals, and the decisions of the Departmental Appeals Board (DAB).

The Division of Program Innovation provides leadership and direction in program development, innovation, and research. It defines critical issues for investigation and makes recommendations regarding subject areas for research, demonstration, and evaluation. It administers the Bureau's discretionary grant programs and awards project grants to state and local agencies and organizations nationwide.

The Division of Child Welfare Capacity Building provides leadership

and direction in the areas of training, technical assistance, and information dissemination under titles IV–B and IV–E of the Social Security Act, and under CAPTA. Either directly or through grants or contracts, it provides training and technical assistance to assist service providers, state and local governments, and tribes. It manages discretionary training grants under section 426 of the Social Security Act and title IV–E training and directs the operations and activities of statutorily mandated clearinghouses. The Division identifies best practices for treating vulnerable families and preventing abuse and neglect. It participates in the development of funding opportunity announcements and manages certain discretionary grant projects.

The Division of State Systems (DSS) reviews, assesses, and inspects the planning, design, and operation of state management information systems and approves advanced planning documents for automated data systems. The Division provides leadership for the provision of technical assistance to states on information systems projects and advances the use of computer technology in the administration of child welfare and social services programs by states. The Division reviews, analyzes, and approves/disapproves state requests for federal financial participation for automated systems development and related activities that support child welfare programs, including foster care and adoption. It provides assistance to states in developing or modifying automation plans to conform to federal requirements, monitors approved state system development activities, and conducts periodic reviews to ensure state compliance with regulatory requirements applicable to automated systems supported by federal financial participation. It provides guidance to states on functional requirements for these automated information systems.

The Division of Performance Measurement and Improvement provides oversight in the collection, analysis, and reporting of state-level data reported to CB through mandated data collections; oversees an outcomes-oriented review of state child welfare systems; and sets, tracks, and reports on performance indicators in response to the Government Performance and Results Act and other performance-oriented mandates. The Division is comprised of two teams. The Data Analytics and Reporting Team collects, analyzes, and disseminates program data from the Adoption and Foster Care Analysis and Reporting System (AFCARS), the National Youth in

Transition Database (NYTD), and the National Child Abuse and Neglect Data Systems (NCANDS); ensures accuracy of data reporting; develops systematic methods of measuring the impact and effectiveness of various child welfare programs; and performs statistical sampling functions. The Child and Family Services Review Team, in partnership with CB's Regional Program Units, carries out reviews of child protection, foster care, adoption, family preservation, family support, and independent living services provided by the states. The Child and Family Services Review Team ensures the accuracy and consistency of the review protocol across all states of the review process and in subsequent program improvement efforts.

C. The Family and Youth Services Bureau (FYSB) is headed by an Associate Commissioner who recommends policy direction and programs to address issues involving vulnerable, at-risk youth and their families to the Commissioner, ACYF. FYSB supports the organizations and communities working to prevent and respond to youth homelessness, youth at risk of trafficking and sexual exploitation, and promote positive adolescent health and development through programs that provide shelter, community services, and prevention education for youth, adults, and families.

A Deputy Associate Commissioner supports the Associate Commissioner and manages the day-to-day operations of FYSB. The Bureau assesses and recommends policies, data and performance measures, and legislation and develops program initiatives to support youth who have or are at-risk of leaving home due to family conflict or other crisis, youth experiencing or at risk of experiencing homelessness or sexual exploitation, and adolescent development and wellbeing. FYSB recommends budgetary and legislative proposals, operational planning initiatives, and projects and subject areas for research, evaluation, and demonstration activities. FYSB coordinates efforts with and provides expert advice to departmental and other federal agencies on supporting vulnerable youth, including youth who have run away from home due to family conflict or other crises, youth experiencing or at risk of experiencing homelessness or housing instability; youth at risk of trafficking, sexual exploitation, or violent crime victimization; youth at risk of unplanned pregnancy or becoming teen parents; and any youth in at-risk situations. FYSB represents HHS on

various councils, workgroups, and committees and provides leadership and coordination to other HHS programs and Federal agencies working to address youth homelessness, youth at risk of trafficking and sexual exploitation, and positive adolescent development and wellbeing. The Bureau is comprised of three Divisions:

The Division of Data, Performance, and Policy (DPP) provides leadership and direction for FYSB, informing program and policy development and innovation through evaluation strategies and data analysis for youth experiencing or at risk of homelessness, youth at risk of trafficking, adolescent pregnancy prevention, and promotion of adolescent health and wellbeing. The Division leads the management of the legislatively mandated data information systems and all evaluation efforts within FYSB. The Division directs evaluation efforts to include study design; instrument development; and rigorous, methodological approaches; and conducts analysis of data to inform the policy and program priorities of FYSB programs. The Division develops and implements FYSB's standard measures for evaluating program performance for the improvement of services to vulnerable populations. It oversees collection of FYSB's performance standards and performance measurement process, evaluation strategies, development of program outcomes, and the synthesis of data to inform and support innovation for each program. The Division provides leadership and direction in policy development and policy analysis of legislation and budget proposals, responds to requests for policy clarification, and assesses the impact of authorizing legislations on FYSB's programs. The Division provides recommendations to the Associate Commissioner and Deputy Associate Commissioner on strategic priorities, policy direction, and programmatic improvements to address issues impacting vulnerable youth and their families and adolescent health and wellbeing. The Division also works collaboratively across ACF and with strategic partnerships and identifies issue areas for evaluation, research, and demonstration initiatives.

The Division of Positive Youth Development administers an array of prevention services to address the wellbeing of adolescents by funding projects to states, tribes, and community-based organizations to provide education to youth (and their families) on how to prevent teen pregnancy and the spread of sexually transmitted infections, including HIV/

AIDS, and skills training to promote healthy relationships and healthy life skills. The Division supports the implementation of evidence-based, age-appropriate, and medically accurate models, including intervention strategies that support the successful transition of youth through adolescence and into adulthood with a holistic approach to teaching the benefits of healthy decision-making, healthy relationships, and mental health and wellbeing. The Division provides technical support to ensure compliance with programmatic and fiscal requirements of programs across all funding streams, as directed by the application of federal policy, regulations, and laws. The Division researches and develops conceptual models pertaining to adolescent sexual health and wellbeing, monitors funded programs, and ensures the provision of technical assistance and training through contracts, cooperative agreements, and Interagency Agreements. This includes the development and management of a social media marketing campaign to provide messaging to youth on positive adolescent development and wellbeing.

The Division of Runaway and Homeless Youth administers prevention, crisis response, shelter, and supportive services to youth and young adults who have run away from home due to family conflict or other crisis or are experiencing homelessness or housing instability. The Division administers the runaway and homeless youth program that incorporates the Basic Center, Street Outreach, Transitional Living, and Maternity Group Home programs. The Division also conducts development and implementation of policy, guidance, and regulations concerning the funding and management of service projects for youth in compliance with the Runaway and Homeless Youth Act. The Division designs, develops, funds, and monitors support activities related to RHY programs including, but not limited to, the provision of technical assistance, executing a monitoring system, maintaining a requisite data collection system, the Runaway and Homeless Youth Training and Technical Assistance Center, the National Clearinghouse on Homeless Youth and Families, and the National Runaway Safeline. The Division oversees the receipt and review of applications for discretionary grants in these program areas and monitors the management of these grants through monthly contacts and on-site visits through the ACF Regional Offices.

III. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

IV. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

V. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023-05366 Filed 3-20-23; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2019-E-3293 and FDA-2019-E-3294]

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

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 MULPLETA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of 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 may submit either electronic or written comments and ask for a redetermination by May 22, 2023. 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 September 18, 2023. 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 May 22, 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 Nos. FDA-2019-E-3293 and FDA-2019-E-3294 for “Determination of Regulatory Review Period for Purposes of Patent