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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, 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 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 BEVYXXA (betrixaban maleate), which is indicated for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE. Subsequent to this approval, the USPTO received patent term restoration applications for BEVYXXA (U.S. Patent Nos. 6,376,515; 6,835,739; 7,598,276; and 8,518,977) from Millennium Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 5, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BEVYXXA 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 BEVYXXA is 4,244 days. Of this time, 4,001 days occurred during the testing phase of the regulatory review period, while 243 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:* November 11, 2005. The applicant claims November 30, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 11, 2005, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 24, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for BEVYXXA (NDA 208383) was initially submitted on October 24, 2016.

3. *The date the application was approved:* June 23, 2017. FDA has verified the applicant's claim that NDA 208383 was approved on June 23, 2017.

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 821 days, 1,531 days, or 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: August 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18788 Filed 8–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1903]

Modernizing Pharmaceutical Quality Systems; Studying Quality Metrics and Quality Culture; Quality Metrics Feedback Program; Reopening of Submission Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of submission period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the submission period for the notice entitled ''Modernizing Pharmaceutical Quality Systems; Studying Quality Metrics and Quality Culture; Quality Metrics Feedback Program'' that published in the **Federal Register** of June 29, 2018. The Agency is taking this action to allow interested persons additional time to participate in the program.

DATES: FDA is reopening the submission period for the notice published on June 29, 2018 (83 FR 30748). Submit written

requests to participate in the program by December 30, 2019 to ensure that the Agency considers your participation in this program.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6649, Silver Spring, MD 20993, 301–796–3257, *Tara.Gooen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 29, 2018 (83 FR 30748), FDA published a notice with a 1-year and 30-day period to submit a request to participate in the ''Modernizing Pharmaceutical Quality Systems; Studying Quality Metrics and Quality Culture; Quality Metrics Feedback Program.'' FDA is reopening the submission period until December 30, 2019. The Agency believes that an additional 120 days will allow adequate time for interested persons to participate without compromising the program.

To be considered for the program, a company should submit a statement of interest for participation to *OPQ-OS-QualityMetrics@fda.hhs.gov.* The statement of interest should include agreement to the selection qualities listed in 83 FR 30748 at 30749–30750, section III.A.

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18771 Filed 8–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of The Assistant Secretary for Planning and Evaluation; Statement of Organization, Functions, and Delegations of Authority

Part A (Office of the Secretary), Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AE, Office of the Assistant Secretary for Planning and Evaluation (ASPE), as last amended at 76 FR 59399 on September 26, 2011. This notice better aligns office titles with program activities, consolidates key functions and clearly delineates ASPE's portfolio within three of its five components; Science and Data Policy (AEJ), Human Service Policy (AES), and Disability, Aging, and Long-Term Care Policy (AEW):

I. Under Section AE.20 Functions, delete the following sections in their entirety.

A. Division of Data Policy (AEJ1)
B. Division of Science Policy (AEJ2)
C. Division of Economic Support for Families (AES)
D. Office of Disability, Aging and Long-Term Care Policy (AEW)
E. Division of Long-Term Care Policy (AEW3)
F. Division of Behavioral Health and Intellectual Disabilities (AEW4)

II. Under Section AE.20 Functions, insert the following sections:

A. The Division of Evidence, Evaluation, and Data Policy (AEJ1) is responsible for evidence and evaluation based policy activities in addition to data and information privacy policy, health information technology and interoperability and data standards; and convenes the Evaluation and Evidence Council to work with stakeholders to implement statutory evidence-building plan requirements.

B. The Division of Science and Public Health Policy (AEJ2) is responsible for supporting Health and Human Services science and public health agencies in areas related to policy coordination, long-range planning, legislative development, economic, program, and regulatory analysis.

C. The Division of Strategic Planning (AEJ3) is responsible for enterprise-wide reporting, implementation, and development of strategic plans related to critical health, public health, and human services programs.

D. The Division of Family and Community Policy (AES1) is responsible for human services policy and programs to improve the wellbeing and economic status of families and communities including economic mobility; social capital; program alignment and coordination at the federal, state, and local levels refugee resettlement; fatherhood; marriage; domestic violence issues; and promoting self-sufficiency and employment including the TANF and Child Support programs.

▪ The Division of Children and Youth Policy (AES2) is responsible for promoting healthy development of children and youth including strategic coordination of national youth policy and positive youth development, child welfare and child protection, and child care and early childhood education.

▪ The Division of Data and Technical Analysis (AES3) is responsible for providing data analytic capacity for policy development and program improvement on cross-cutting human services policy through data analysis, modeling, cost and impact analyses, and the enhancement of national, state, and local data sources for analyzing and managing issues. The division also is responsible for the annual update of the HHS poverty guidelines, and also maintains cognizance of data collection activities of the Federal statistical system and coordinates with the Office of Science and Data Policy (AEJ), as appropriate.

E. The Office of Behavioral Health, Disability, and Aging Policy (AEW) is responsible for the development, coordination, research and evaluation of HHS policies and programs that support the independence, productivity, health and wellbeing of children, working age adults, and older adults with mental health and substance use disorders (*i.e.* behavioral health) and other disabilities.

▪ The Division of Disability and Aging Policy (AEW1) is responsible for the policy development, coordination, research and evaluation of federal policies and programs that aim to address the needs of people with disabilities and older Americans. Areas of focus include the interaction between the health, disability, and economic well-being of persons of all ages with disabilities including the prevalence of disability and disabling conditions; describing the socio-demographic characteristics of relevant populations; determining service use, income, employment, and program participation patterns; and coordinating the development of disability and aging data and related policy.

F. The Division of Long-Term Services and Supports Policy (AEW3) is responsible for policy development and analysis related to disability, aging, and long-term services and supports components of Medicare, Medicaid, nursing facility services, community residential, personal, and home and health rehabilitation, and the integration of acute and post-acute care services, including for individuals dually-eligible for Medicare and Medicaid.

G. The Division of Behavioral Health Policy (AEW4) is responsible for the analysis, coordination, and research and evaluation of policies related to behavioral, mental, and substance use disorders. The division is the focal point for policy development and analysis related to the financing, access/delivery, organization, and quality of services for people with behavioral, mental, and substance use disorders, including those supported or financed by Medicaid, Medicare, and SAMHSA.

III. Delegations of Authority: All delegations and redelegations of authority made to officials and employees of affected organizational