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 [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] 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 [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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.

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