WINSTON & STRAWN LLP

CLIENT ALERT

FDA Announces Innovative Quality Management Maturity Pilot Programs for Manufacturers of Drug Products and Active Pharmaceutical Ingredients

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On October 15, 2020, the Food and Drug Administration (FDA or the Agency) Center for Drug Evaluation and Research announced two new Pilot Programs to gain insight into the quality management systems of domestic drug product manufacturers and foreign active pharmaceutical ingredient (API) manufacturers. The third-party assessments from each Pilot Program will help FDA develop a future rating system to characterize quality management maturity (QMM).

FDA aims to create an industry rating system that would characterize QMM and incentivize investments in quality manufacturing. Manufacturers that choose to disclose their facility ratings could benefit from a competitive advantage, as knowledge of QMM ratings would enable health systems and other purchasers and payers of medications to differentiate among drug manufacturers. Likewise, API manufacturers that choose to disclose their facility ratings to drug product manufacturers could benefit from a competitive advantage, as knowledge of QMM ratings would enable drug product manufacturers to differentiate among facilities when purchasing APIs.

FDA notes that it will accept requests to participate in the QMM Finished Dosage Forms and QMM Active Pharmaceutical Ingredients Pilot Programs through November 30, 2020, and the Programs will run through December 31, 2021.

See Announcements Regarding Quality Management Maturity Pilot Programs, *available at* https://public-inspection.federalregister.gov/2020-22976.pdf?utm_medium=email&utm_source=govdelivery and https://public-inspection.federalregister.gov/2020-22977.pdf?utm_medium=email&utm_source=govdelivery.

Quality Management Maturity Pilot Program for Finished Dosage Forms

FDA's announcement of the QMM Pilot Program for Finished Dosage Forms (FDF) serves as an invitation for interested domestic drug product manufacturers of prescription and over-the-counter drug products to submit a request to participate.

FDA will select up to nine participants for this Pilot Program, and a third-party contractor identified by FDA will conduct an assessment of each participant's quality management system while accompanied by FDA staff. Assessments will cover multiple topics including but not limited to: supply chain management; manufacturing

strategy and operations; safety, environmental, and regulatory compliance; inventory management; performance management and continual improvement; risk management; management review and responsibility; planning; workforce management; quality culture; and customer experience.

To be considered for the Program, participants must:

a. Be a United States-based manufacturing facility of prescription and/or over-the-counter drug products.

b. Have received a final classification of "No Action Indicated" or "Voluntary Action Indicated" on all FDA inspection(s) of the manufacturing facility conducted within the five years prior to October 1, 2020.

c. Agree to permit a third-party contractor to conduct a QMM assessment, on-site or remotely. FDA will identify an external contractor and FDA will join the contractor for the assessment.

d. Agree to collect and submit metrics data to FDA before the assessment.

e. Agree to be available for consultations with the contractor and FDA before and after the assessment, including discussions regarding the participant's established QMM-related activities and the contractor's post-assessment recommendations regarding these activities.

Quality Management Maturity Pilot Program for Active Pharmaceutical Ingredients

FDA's QMM Pilot Program for Active Pharmaceutical Ingredients is for interested facilities located outside the United States that manufacture APIs, including facilities manufacturing drug substance intermediates used to produce APIs for use in FDA-regulated prescription and over-the-counter drug products. As with the QMM Pilot Program for FDF, FDA will select up to nine participants and will seek insight from third-party assessments of each participant's QMM, allowing for a cross-sectional comparison of facilities.

Assessments will review supply chain management; manufacturing strategy and operations; safety, environmental, and regulatory compliance; risk management; and quality culture, among other topics.

To be considered, participants must:

a. Be a facility located outside the United States that manufactures APIs or drug substance intermediates used to produce APIs for FDA-regulated prescription and over-the-counter drug products.

b. Have received a final classification of "No Action Indicated" or "Voluntary Action Indicated" on all FDA inspection(s) over the last five years.

c. Agree to: (1) permit a third-party contractor to conduct a QMM assessment (on-site or remotely); (2) collect and submit metric data to FDA and the contractor by an agreed-upon date that is prior to the assessment; and (3) be available for consultations with the contractor and FDA prior to and after the assessment.

FDA believes that there has been significant progress in enhancing and modernizing the regulation of pharmaceutical manufacturing and product quality. These Pilot Programs are yet another step in implementing a modern, risk-based pharmaceutical quality-assessment system without extensive regulatory oversight. Participation is voluntary. Please reach out to your Winston relationship attorney to learn more.

We note that government orders on the local, state, and federal levels are changing every day, and the information contained herein is accurate only as of the date set forth above.

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For further information or questions on FDA's QMM Pilot Programs or to submit a request to participate with Winston & Strawn, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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