

Market Briefing

Melrose Park Regulatory Update

The FDA Warning Letter reflects the Form 483 observations Fresenius Kabi received following the February 2026 inspection of the Melrose Park facility. No patient safety concerns related to the observations have been identified. The facility remains fully operational. As communicated during the Q2/26 earnings call, no material impact on production, supply, or full-year financial performance in 2026 is expected.

Operational status and financial impact

As previously communicated, the FDA classified the site as Official Action Indicated, or OAI, in June 2026. The observations are largely associated with quality-system processes related to the transfer of manufacturing capabilities from a legacy facility to a new facility at the Melrose Park site. The Warning Letter may potentially affect the timing of approvals for a small number of new products intended to be manufactured at Melrose Park until the observations have been satisfactorily addressed.

Production network offers flexibility

Fresenius Kabi has a broad manufacturing network and operational flexibility. The company is evaluating mitigation measures across its network, including options to support selected future product launches at alternative US facilities, where technically and regulatorily feasible.

Maintaining reliable supply and avoiding drug shortages remain key priorities. Fresenius Kabi is working closely with the FDA to support the continued supply of essential medicines throughout the remediation process.

Implications

As previously communicated as part of the Q2/26 earnings release, this regulatory action represents a specific and manageable operational matter and does not change Fresenius Kabi's long-term outlook for its manufacturing network. Fresenius Kabi continues to work closely and constructively with the FDA as the process progresses.

The company has multiple operational levers available to manage production and supply, if required, and is evaluating mitigation measures across its broader manufacturing network. Fresenius will provide further information if the assessment changes materially.

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