
Summary of McKesson's Response to the FDA's Feb. 7 Warning Letter

McKesson Corporation is committed—to the fullest extent—to doing its part to safeguard the United States drug supply against suspect, illegitimate, counterfeit, stolen, or diverted product. The Company has conducted a comprehensive review of the Warning Letter related to FDA's inspection of its corporate headquarters located in San Francisco and one of its distribution centers in Wilsonville, Oregon. We take very seriously the issues identified and are committed at the highest levels of the Company to addressing FDA's concerns and enhancing our Drug Supply Chain Security Act ("DSCSA") compliance program. This enhancement effort has been, and will continue to be, multi-faceted, including actions previously taken immediately after issuance of the FDA 483 in July 2018, as well as a series of additional actions, elaborated below, that the Company is committing to take to address our obligations in ways that will help ensure long-term sustainability and agility as further regulatory guidance and best practices emerge. Most importantly, our enhanced procedures, dedicated review team, and systematic approach are intended to ensure that we remain an important and reliable partner to the FDA in securing the integrity of the pharmaceutical supply chain in this country.

We understand that the specific incidents referenced in the Warning Letter and the underlying FDA 483 issued on July 3, 2018, are only examples of deficiencies with respect to the verification requirements that must be met by pharmaceutical wholesale distributors. Furthermore, McKesson US Pharmaceutical and each of its twenty-nine (29) distribution centers (hereinafter "McKesson") also understands that the information provided during the inspection and in response to the FDA 483 did not provide sufficient information about the incidents of suspect product that the FDA cited or the actions we took to enhance our DSCSA compliance program and to ensure the integrity of the supply chain since the inspection. With this Warning Letter response, we seek to do both.

Specifically, to address the Warning Letter findings, this letter provides details about the steps McKesson took following FDA's Observations in July of 2018 to strengthen the ability to protect the supply chain from suspect and illegitimate product: (1) we will describe the policies and standard operating procedures ("SOPs") that were enhanced following the FDA Inspection and put in place in all twenty-nine of McKesson's distribution centers; (2) we will explain the training program that was taken by nearly 4,000 McKesson employees by the end of 2018 regarding the revised policies and SOPs; and (3) we will walk through the centralized oversight, documentation, and notification efforts that were implemented in 2018 in response to the FDA's Observations.

And looking forward, this letter details the rigorous and systematic approach the Company intends to take: (1) by engaging a highly qualified independent consultant to assess our program and help us rapidly address any gaps that may be identified; and (2) by implementing a Compliance Action Plan with support and oversight from the highest levels of the company, including the Compliance Committee of the Company's Board of Directors. Finally, this letter clarifies the concrete steps McKesson took in response to the specific examples given in the Warning Letter, and explains how our newly adopted procedures have enhanced our ability to respond if similar situations arose today.

We recognize that our responses to FDA's 483 Observations did not include sufficient detail describing McKesson's efforts to investigate the incidents FDA cited in the Warning Letter and acknowledge that its representative did not convey the correct summary of procedures and practices regarding DSCSA compliance during the FDA inspection. As described in this letter, we have taken steps since the issuance of the FDA 483 to enhance our program, and we have committed to augment these recent efforts to ensure lasting, sustainable change. The integrity of the supply chain depends on a strong partnership between the government and the private sector. We are strongly committed to working closely with the FDA to ensure that we are living up to both the spirit and requirements of the DSCSA.

We are also mindful of the ongoing epidemic of drug abuse in our nation, which includes the abuse of prescription drugs. Over the past decade, as the opioid epidemic evolved, we enhanced our teams, processes, and technologies dedicated to preventing diversion of prescription medications. We are committed to maintaining, and continuously enhancing, strong programs designed to detect and prevent opioid diversion within the pharmaceutical supply chain, while also protecting the availability of appropriate treatments for patients with serious illnesses and injuries. We expect the enhancements to our DSCSA compliance program to further bolster our efforts to prevent abuse of prescription drugs.

We appreciate the opportunity to respond to the Warning Letter and provide details of actions we have taken and intend to take to secure the integrity of the supply chain. We would also welcome an in-person meeting to address any questions about the details we are providing, and to hear any observations the FDA has about best practices for complying with the DSCSA.