

Drug Distributor McKesson Receives Warning Letter from FDA for Allegedly Shipping ?Illegitimate? Opioids

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Major drug distributor McKesson has received a warning letter from the Food and Drug Administration for allegedly shipping ?illegitimate? opioid products. The FDA accuses McKesson of failing to identify, investigate, and stop people from tampering with opioid shipments.

According to the FDA, the warning letter was sent to McKesson because the drug distributor failed to properly handle and investigate incidents related to the tampering of their products.

The FDA was specifically making the accusation that McKesson was failing to keep the situation under control by not identifying, investigating and stopping opioid shipments that have been tampered with. Some of the shipments were discovered at three Rite Aid pharmacies in Michigan.

It is worth noting that this is the first warning letter issued by the FDA under the 2013 Drug Supply Chain Security Act.

In the midst of an opioid crisis, distributors have been coming under fire for their role in the epidemic.

McKesson, as well as Cardinal health, are the subject of numerous lawsuits concerning opioid distribution. These lawsuits accuse the distributors of ?flooding? communities with the medications. Click the link to see Cincinnati's top rehab placement programs.

?A distributor's failure to have systems in place to investigate and quarantine suspect and illegitimate products within their control is a violation of the law. But this is even more concerning given that we're in the midst of a widespread opioid crisis,? FDA Commissioner Scott Gottlieb said in a statement.

In its warning letter, the FDA referenced three instances where McKesson shipped prescription drugs that were supposed to be opioids and pharmacies discovered the opioid pills were removed and replaced with other products.

In September and October 2016, three Rite Aid pharmacies in Michigan received bottles of oxycodone hydrochloride that were instead filled with naproxen. In one other case, the bottles were filled with naproxen and ciprofloxacin hydrochloride.

McKesson investigated the incidents, but according to the FDA, the company did not demonstrate that it identified all illegitimate products. The distributor also failed to notify its other customers who might have received products from the same batch.

McKesson responded through a statement that it takes the situation ?very seriously?. ?We have been in communication with the FDA over the past several months to respond to their questions and we are in the process of providing additional procedural detail and documentation, including enhancements recently made in response to the FDA's initial feedback,? said the company. ?We are committed to the security of the supply chain and are taking steps to help ensure we comply fully with FDA's track-and-trace laws for all pharmaceutical products.?

The warning letter serves as the first step in any of The Food and Drug Administration?s regulatory actions that it may take against a company, when in violation of certain laws. The FDA is open to taking possible legal action. This includes seeking an injunction if McKessen is unable to respond properly.

The distributor now has 15 days from the time it receives the letter to outline the steps it has taken to correct the violations flagged by the FDA. McKessen also has to identify and conduct investigations related to other reports of suspicious or illegitimate shipments.

Each year, more and more people are dying from an opioid-related overdose. If someone in the family is struggling with opioid addiction, it is important to seek help. A combination of medical detox and behavioral therapy can go a long way in the fight against drug abuse. But because every individual is affected by

addiction differently, a comprehensive program tailored to their specific needs is necessary. Look for a nearby addiction treatment facility today and find out how drug treatment programs work.

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