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US FDA requests Endo Pharmaceuticals to remove Opana ER for risks related to abuse

12 June 2017 | News

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USFDA has requested Endo Pharmaceuticals to remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market based on the concern that the benefits of drug may be no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse.

Scott Gottlieb, FDA Commissioner, M.D. said, “We are facing an opioid epidemic – a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse. We will continue to take regulatory steps when we see situations where an opioid product’s risks outweigh its benefits, not only for its intended patient population but also in regard to its potential for misuse and abuse.”

The FDA’s decision is based on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product’s reformulation. Injection abuse of reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy).

Opana ER was first approved in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting.

Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research said, "The abuse and manipulation of reformulated Opana ER by injection has resulted in a serious disease outbreak. When we determined that the product had dangerous unintended consequences, we made a decision to request its withdrawal from the market. This action will protect the public from further potential for misuse and abuse of this product."