Generic Name:
Oxymorphone hydrochloride
Trade Name:
Reformulated Opana ER
Company:
Endo Pharmaceuticals
Notes:

On June 8, 2017, FDA requested that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market. After careful consideration, the agency is seeking removal because of concerns that the benefits of the drug may 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 because of the public health consequences of abuse.

FDA?s decision was 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).

This decision follows a March 2017 FDA advisory committee meeting in which a group of independent experts voted 18-8 that the benefits of reformulated Opana ER no longer outweigh its risks.

Opana ER was first approved in 2006 for 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.

While the product met the regulatory standards for approval, FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company?s request to include labeling describing potentially abuse-deterrent properties for Opana ER. Now, with more information about the risks of the reformulated product, the agency is taking steps to remove the reformulated Opana ER from the market.

FDA has requested that the company voluntarily remove reformulated Opana ER from the market. Should the company choose not to remove the product, the agency intends to take steps to formally require its removal by withdrawing approval. In the interim, FDA is making health professionals and others aware of the particularly serious risks associated with abuse of this product.

FDA said it will continue to examine the risk?benefit profile of all approved opioid analgesic products and take further actions as appropriate as a part of its response to this public health crisis.

Medication Monitor Categories:
Product Withdrawals
