

FDA outlines standards for anti-abuse generic painkillers (Update)

March 24 2016, by Matthew Perrone



This Oct. 14, 2015, file photo, shows the Food & Drug Administration campus in Silver Spring, Md. Federal officials are encouraging generic drugmakers to reformulate their painkillers to make them harder to abuse, the latest in a string of steps designed to combat abuse of highly-addictive prescription pain drugs. On Thursday, March 24, 2016, the FDA published draft guidelines outlining testing standards for harder-to-abuse generic painkillers. (AP Photo/Andrew Harnik, File)

Federal officials are encouraging generic drugmakers to develop

painkillers that are harder to abuse, the latest in a string of steps designed to combat abuse of highly-addictive pain drugs like codeine and oxycodone.

The Food and Drug Administration published draft guidelines outlining testing standards for harder-to-abuse generic painkillers. The agency has already approved five brand-name opioid pain drugs which are designed to discourage abuse. The current version of OxyContin, for example, is difficult to crush, discouraging abusers from snorting or dissolving the tablets to get high.

But these abuse-deterrent painkillers represent a small fraction of the market for opioid pain drugs, which is dominated by low-cost generics.

Generic drugs receive a streamlined review process at the FDA, which helps speed their path to market and reduce the prices passed onto consumers. Generally, manufacturers only need show that their products are chemically equivalent to the original version. In addition, the FDA draft guidelines released Thursday make clear that companies will need to perform additional studies showing that generic opioids have the same anti-abuse properties as their brand-name counterparts.

FDA officials said there is no timeline for updating currently-available generic opioids to abuse-deterrent versions.

Thursday's proposal comes just days after the FDA said it would add a new boxed warning—the most serious type—to some 175 immediate-release painkillers, including both branded and generics.

That action is one in a series of measures promised by new FDA Commissioner Dr. Robert Califf, who was confirmed by the Senate last month.

Califf's confirmation was held up by Senate lawmakers who said the agency needed to do more to combat opioid abuse. For years, the agency only made modest changes to the drugs, emphasizing the need to keep medications accessible to patients with chronic pain.

In its announcement, the FDA acknowledged that evidence on the benefits of abuse-deterrent opioids is still emerging.

"We recognize that abuse-deterrent technology is still evolving and is only one piece of a much broader strategy to combat the problem of opioid abuse," Califf said in a printed statement. "But strongly encouraging innovation to increase access to generic forms of abuse-deterrent opioid medications is an important element in that strategy."

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