

FDA moves toward making overdose antidote an over-the-counter drug

November 16 2022, by Cara Murez



The U.S. Food and Drug Administration appears poised to approve

certain naloxone products for over-the-counter use, a move that would help fight the nation's opioid epidemic.

Naloxone (Narcan, Evzio) can save lives when administered soon after the first signs of an overdose from opioids such as heroin, fentanyl, oxycodone or morphine.

On Tuesday, the FDA [issued](#) a Federal Register notice that could lead to some prescription [naloxone](#) products getting approved for over-the-counter sales. The notice could also encourage development of new nonprescription [naloxone](#) products.

"Today's action supports our efforts to combat the opioid overdose crisis by helping expand access to naloxone," said [FDA Commissioner Dr. Robert Califf](#) in an agency news release. "The agency will keep overdose prevention and reduction in [substance use disorders](#) as a key priority and area of intense strategic focus for action as rapidly as possible."

The notice cites a preliminary assessment that a naloxone nasal spray and an autoinjector "may be approvable as safe and effective for nonprescription use." However, it isn't a final decision or a mandate to make naloxone products available without a prescription.

The FDA said it still needs more data, including packaging and labeling information, before it makes a final recommendation.

In 2021, there were an estimated 107,622 [drug overdose deaths](#) in the United States, according to the U.S. Centers for Disease Control and Prevention. Nearly 81,000 of those were related to opioids.

This is the latest FDA effort to improve access to naloxone products to stop overdoses as they happen. In September, the agency clarified that certain Drug Supply Chain Security Act requirements don't apply to

naloxone.

The FDA has also developed a model drug facts label that includes easy-to-understand pictograms. This is meant to encourage manufacturers to seek approval for over-the-counter naloxone products. Another measure extended the shelf life of naloxone [nasal spray](#) from 24 months to 36 months.

More information: The U.S. Department of Health and Human Services has more on the [opioid epidemic](#).

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