

# FDA approves second OTC naloxone spray for suspected opioid overdose

August 4 2023, by Lori Solomon

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The U.S. Food and Drug Administration has approved [RiVive](#), an over-

the-counter (OTC) naloxone hydrochloride nasal spray for emergency treatment of known or suspected opioid overdose.

"We know naloxone is a powerful tool to help quickly reverse the effects of opioids during an overdose. Ensuring naloxone is widely available, especially as an approved OTC product, makes a critical tool available to help protect [public health](#)," FDA Commissioner Robert M. Califf, M.D., said in an agency news release. "The agency has long prioritized access to naloxone products, and we welcome manufacturers of other naloxone products to discuss potential nonprescription development programs with the FDA."

The approval was based on data that showed similar levels of RiVive reach the bloodstream as an approved prescription naloxone product. Additionally, the drug was shown to be safe and effective. Finally, the manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a health care professional.

"Every step taken to increase the availability of safe and effective opioid-related overdose-reversal medications will save lives," Bobby Mukkamala, M.D., chair of the American Medical Association Substance Use and Pain Care Task Force, said in a [statement](#). "There is no medical or ethical reason for naloxone manufacturers to delay submitting these applications."

The FDA previously approved the first nonprescription naloxone [nasal spray](#) product in March 2023 and the first generic nonprescription naloxone nasal spray product in July 2023.

**More information:** [More Information](#)



Citation: FDA approves second OTC naloxone spray for suspected opioid overdose (2023, August 4) retrieved 29 April 2024 from <https://medicalxpress.com/news/2023-08-fda-otc-naloxone-spray-opioid.html>

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