FDA approves higher dosage of Naloxone nasal spray to treat opioid overdose

The U.S. Food and Drug Administration announced today the approval of a higher dose naloxone hydrochloride nasal spray product to treat opioid overdose. The newly approved product delivers 8 milligrams (mg) of naloxone into the nasal cavity. The FDA had previously approved 2 mg and 4 mg naloxone nasal spray products.

Naloxone is a medicine that can be administered by individuals with or without medical training to help reduce opioid overdose deaths. If naloxone is administered quickly, it can counter the opioid overdose effects, usually within minutes. A higher dose of naloxone provides an additional option in the treatment of opioid overdoses.

“Today’s action meets another critical need in combatting opioid overdose,” said Patrizia Cavazzoni, M.D., director of the FDA’s Center for Drug Evaluation and Research. “Addressing the opioid crisis is a top priority for the FDA, and we will continue our efforts to increase access to naloxone and place this important medicine in the hands of those who need it most.”

Over the last several years, the FDA has taken a number of steps to improve availability of naloxone products, including: encouraging manufacturers to pursue approval of over-the-counter naloxone products; requiring drug manufacturers for all opioid pain relievers and medicines to treat opioid use disorder to add new recommendations about naloxone to the prescribing information; and extending the shelf life of naloxone nasal spray from 24 months to 36 months.

The FDA is committed to using its regulatory authority to

address the opioid crisis with a focus on: decreasing exposure to opioids and preventing new addiction; fostering the development of novel pain treatment therapies; supporting treatment of those with opioid use disorder; and improving enforcement and assessing benefit-risk.

The use of naloxone in patients who are opioid-dependent may result in opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure.

The FDA granted approval of KLOXXADO to Hikma Pharmaceuticals through the 505(b)(2) approval pathway under the Federal Food, Drug, and Cosmetic Act. A new drug application submitted through this pathway may rely on the FDA's finding that a previously approved drug is safe and effective or on published literature to support the safety and/or effectiveness of the proposed product, if such reliance is scientifically justified. In this case, the manufacturer submitted a 505(b)(2) application that relied, in part, on the FDA's finding of safety and effectiveness for naloxone hydrochloride (NARCAN injection) to support approval. The applicant demonstrated that reliance on the FDA's finding of safety and effectiveness for Narcan was scientifically justified and provided KLOXXADO-specific pharmacokinetic data to establish the drug's safety and efficacy for its approved use.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.