FDA NEWS RELEASE

FDA Takes Steps to Restrict 7-OH Opioid Products Threatening American Consumers

Agency alerts health care professionals and consumers of 7-hydroxymitragynine risks

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For Immediate Release:

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The U.S. Food and Drug Administration today is taking a bold step to protect Americans from dangerous, illegal opioids by recommending a scheduling action to control certain 7-hydroxymitragynine (also known as 7-OH) products under the Controlled Substances Act (CSA).

The FDA is specifically targeting 7-OH, a concentrated byproduct of the kratom plant; it is not focused on natural kratom leaf products. 7-OH is increasingly recognized as having potential for abuse because of its ability to bind to opioid receptors. The FDA is releasing a new report (https://www.fda.gov/media/187899/download?attachment) to educate the public about the health concerns of 7-OH and its distinction from the kratom plant leaf.

“Today, we’re taking action on 7-OH as a critical step in the fight against opioid addiction,” **said HHS Secretary Robert F. Kennedy, Jr**. “We will protect the health of our nation’s youth as we advance our mission to Make America Healthy Again.”

This recommendation follows a thorough medical and scientific analysis by the FDA and is one of several efforts to address the agency’s concerns around the growing availability and use of 7-OH opioid products. There are no FDA-approved 7-OH drugs, 7-OH is not lawful in dietary supplements and 7-OH cannot be lawfully added to conventional foods.

“Vape stores are popping up in every neighborhood in America, and many are selling addictive products like concentrated 7-OH. After the last wave of the opioid epidemic, we cannot get caught flat-footed again,” **said FDA Commissioner Marty Makary, M.D., M.P.H.** “7-OH is an opioid that can be more potent than morphine. We need regulation and public education to prevent another wave of the opioid epidemic.”

The availability of 7-OH products is a major concern to the FDA, as consumers can easily purchase products with concentrated levels of 7-OH online and in gas stations, corner stores and vape shops. The FDA is particularly concerned with the growing market of 7-OH products that may be especially appealing to children and teenagers, such as fruit-flavored gummies and ice cream cones. These products may not be clearly or accurately labeled as to their 7-OH content and are sometimes disguised or marketed as kratom. The FDA has also published educational materials (https://www.fda.gov/media/187900/download) for consumers to be more informed about these harmful products.

In June, the FDA issued warning letters to seven companies for illegally distributing products containing 7-OH, including tablets, gummies, drink mixes and shots. Today, the FDA is also issuing a letter to health care professionals (https://www.fda.gov/media/187898/download?attachment) and is warning consumers (https://www.fda.gov/drugs/information-consumers-and-patients-drugs/hiding-plain-sight-7-oh-products) about the risks associated with 7-OH products.

Under the CSA, drugs, substances and certain chemicals are placed into one of five schedules based upon their medical use, potential for abuse and safety or dependence liability. The Drug Enforcement Administration is reviewing the recommendation and has the final authority on scheduling, which requires a rulemaking process that includes a period for the public to provide comments before any scheduling action is finalized.

Related Information

- Hiding in Plain Sight: 7-OH Products (/news-events/public-health-focus/hiding-plain-sight-7-oh-products)

Media:
HHS Request for Comment (https://www.hhs.gov/request-for-comment-form/index.html?Agency=ASPA)
202-690-6343

Consumer:
888-INFO-FDA

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