

## Stop Street drug alternative: FDA warns

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**FDA warns companies for promoting Coco Loko, a snortable chocolate powder, and Legal Lean, a drink, as alternatives to street drugs.**



The U.S. Food and Drug Administration posted a warning letter to the marketers and distributors of Legal Lean Syrup, a drink, and Coco Loko, a "snortable" chocolate powder, for selling unapproved new drugs and misbranded drugs.

The warning letter explains how the claims made in the promotional materials for Legal Lean Syrup and Coco Loko demonstrate that the products are intended to be used as alternatives to illicit street drugs and that the products, as labeled and marketed, may pose safety concerns.

Drug abuse is a serious public health issue, and the FDA is concerned that products like Legal Lean Syrup and Coco Loko encourage drug abuse in individuals, including minors.

Street drug alternatives are products that claim to mimic the effects of recreational drugs and are intended to be used for recreational purposes to affect psychological circumstances.

"As a physician and a parent, I'm deeply troubled by the unlawful marketing of these potentially dangerous products, especially since they are so easily accessible by minors. Encouraging the use of snortable chocolate as an alternative to illegal street drugs is not acceptable. There are very real consequences to snorting any powder, not to mention the societal dangers of promoting drug abuse," said FDA Commissioner Scott Gottlieb, M.D.

He added further "At a time where drug addiction is threatening the fabric of American society, we must take action when we see efforts that may further fuel illicit drug abuse. We'll continue to vigorously target bad actors that sell unapproved products, including products that contain undeclared drug ingredients."

Coco Loko is described as a "snuff" and promoted to be "snorted" (inhaled intranasally).

Intranasal administration of a powder substance can trigger spasms of the vocal cords making it difficult to speak or breathe (laryngospasm) or tightening of the muscles that line the airways in the lungs (bronchospasm) and may also induce or exacerbate asthma.

The ingredients listed on the product label for Coco Loko also include taurine and guarana, neither of which has been evaluated for intranasal administration.

An FDA laboratory analysis found that Legal Lean Syrup contained the active pharmaceutical ingredient doxylamine, which was not included in the product labeling.

FDA-approved products that contain doxylamine warn against its use with alcoholic beverages and instruct people with certain medical conditions to consult a physician before use.

Furthermore, the inclusion of undeclared doxylamine in Legal Lean Syrup poses a potentially serious risk to those who have already had adverse reactions to this ingredient and whose physicians have advised them to avoid it.

In general, products that contain undeclared drug ingredients pose a serious health risk, because consumers with underlying medical issues may take the products without knowing of any potential side effects or interactions.

The companies have 15 days to respond to the FDA and correct the issues noted, or they may face regulatory action.