

FDA, Concerned About Safety, Explores Regulating CBD in Foods, Supplements

Agency, which is studying the effects of cannabis-derived ingredients, aims to reveal its oversight plans in the coming months

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“Given what we know about the safety of CBD so far, it raises concerns for FDA about whether these existing regulatory pathways for food and

dietary supplements are appropriate for this substance," said FDA Principal Deputy Commissioner Janet Woodcock, who has led the agency's efforts looking at cannabis regulation.

Patrick Cournoyer, who heads the FDA office developing the agency's cannabis strategy, said the agency wants to know whether CBD can be safely eaten every day for a long period or during pregnancy, for example. He pointed to concerns about future fertility.

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Congress legalized hemp and its resulting products in 2018 but left them to the FDA to regulate. Since then, makers of products such as CBD oil have operated [without specific federal rules](#) guiding their manufacture or marketing, while some [states have moved](#) ahead with their own sets of rules.

Large companies have held off investing in the space as they wait for the agency to decide whether any cannabis-derived products can be treated as food or supplements, rather than as drugs. Yet cannabis-derived products [have still proliferated](#): A 2021 report by the FDA said the \$4.6 billion market was expected to quadruple by 2026.


As of now, the agency says CBD and similar chemicals cannot be added to foods or marketed as supplements. If companies make therapeutic claims about their products, they must prove with clinical trials that they meet the agency's standard for new drugs.

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Cannabis plants contain dozens of cannabinoid chemicals, including cannabidiol, or CBD. Another main chemical, known as THC, causes the high associated with marijuana use. Unlike THC, CBD isn't psychoactive. Some researchers and companies say it can ease pain.

Research on cannabinoids is in early stages, according to the National Institutes of Health, which is funding studies exploring how the substance works in the body and its potential to relieve pain. Some evidence suggests CBD may be harmful to some people, the NIH says.

The FDA has approved a [drug named Epidiolex](#) containing CBD for the treatment of certain types of epilepsy in patients 2 years of age and older. When that drug was being tested, some people taking it had sleeplessness or diarrhea, while others had liver problems that forced them to stop taking it, according to the NIH.



As of now, the Food and Drug Administration says, CBD and similar chemicals may not be added to foods or marketed as supplements. Photo: Eric Lee for The Wall Street Journal

After weighing the evidence, the FDA will decide within months how legal cannabis should best be regulated and whether that will require new agency rules or new legislation from Congress, agency officials said.

"I don't think that we can have the perfect be the enemy of the good when we're looking at such a vast market that is so available and utilized," said Norman Birenbaum, a senior adviser in the agency working on the issue. "You've got a widely unregulated market."

The FDA regulates medicines, medical devices, dietary supplements and food, such as infant formula. The agency in recent years began overseeing the manufacture, distribution and marketing of tobacco

products.

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As drinks, snacks and other products containing cannabis have spread, many companies and lawyers have been awaiting the agency's direction before developing their own offerings.

"We still have members that want to get into this space, but they want to do it legally," said Roberta Wagner, vice president of regulatory and technical affairs at the Consumer Brands Association, an industry trade group.

She said the FDA could face challenges if CBD products that have gone on sale without the agency's regulation don't meet future safety standards.

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Aaron Smith, CEO of the National Cannabis Industry Association, a trade group for small cannabis businesses, said federal regulations should complement, rather than contradict, state rules. "The states are decades ahead of the federal government," he said.

Complicating the agency's efforts, officials said, are new cannabinoids, such as the chemical commonly known as Delta-8 that emerged on the market in recent years, and that meet the definition of legal cannabis but are intoxicating.

Mr. Birenbaum said the agency had "growing and more intensifying short-term concerns" about intoxicating hemp-derived products. A

child in Virginia died earlier this year after eating Delta-8 gummies, while teenagers and children in Texas and Iowa were sickened.

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"Over the last year and a half, we have seen a whole host and cadre of intoxicating hemp derived cannabinoids come up," said Mr. Birenbaum. "There are very, very different regulatory considerations for products that are going to intoxicate you."

The FDA said Mr. Birenbaum's conversation with The Wall Street Journal was his first media interview since joining the agency in the fall. He previously led cannabis regulation for the states of New York and Rhode Island.

Meanwhile, the agency is focusing enforcement efforts on products that pose an immediate public-health risk, such as candies that could be accidentally eaten by children, or products meant to be consumed by food-producing animals, officials said.

Mr. Birenbaum said the agency also seeks to educate consumers about potential health consequences of cannabis and the products' varying quality.

"The safety profiles around these products are not what they are generally accustomed to and not the same as what they get from other products when they walk into a wellness store or grocery store or even a gas station," he said.

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