

## FDA Considers Safety of Food Infused With Cannabis Extract

Academics raise concerns; hemp-farmers group asks for help in promoting cannabidiol use

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SILVER SPRING, Md.—The U.S. Food and Drug Administration held its first-ever hearing on the safety and marketing of chemicals from the cannabis plant, with food makers and others in industry urging the agency to approve the ingredient CBD and academics raising safety concerns.

The hearing Friday could lead to an agency decision to allow certain food uses of the chemical. CBD, or cannabidiol, is a hot seller these days, widely used in cocktails, candy and food for people and pets. Yet many such uses are technically illegal under the agency's loosely enforced rules.

As if to underscore the difficulties faced by the agency, acting FDA Commissioner Ned Sharpless said “the various legal requirements vary depending on which type of product we're talking about.”

Cannabis plants include the variety called marijuana—which gets people high—and hemp, which generally doesn't and contains CBD. Hemp is no longer considered a controlled substance by the Drug Enforcement Administration. But because CBD previously was on the controlled-substance list, comparatively little research has been done on it.

“This lack of research, and therefore evidence, to support CBD's broader use in FDA-regulated products, including in foods and dietary supplements, has resulted in unique complexity for its regulation,” Dr. Sharpless said at the hearing.

He posited a case in which someone uses topical CBD lotion, drinks a CBD beverage and eats CBD oil: “What if she's pregnant?” he said. “What if children access CBD products like gummy edibles? What happens when someone chronically uses CBD for prolonged periods?”

Farmers told the FDA officials that they needed to add hemp as a cash crop to compete with China and other big agricultural nations. Jonathan Miller of the U.S. Hemp Roundtable urged the FDA to find a way to help CBD use grow.

The FDA generally says it is illegal to sell products with CBD infused as a food or supplement in interstate commerce, largely because CBD is also a main ingredient in the prescription drug Epidiolex for controlling seizures. But the agency's enforcement of the food and supplement marketing ban appears to be light.

The food-and-supplements industries have moved ahead with CBD products. Chains such as GNC and Walgreens have begun carrying it in certain stores. In all, the CBD food-and-supplements business is expected to snowball to \$5.69 billion in 2019, according to cannabis market-research firm Brightfield Group, which anticipates even more store chains stocking CBD in the coming months.

The legal landscape for CBD products is complicated. Hemp now is legal after passage of last year's farm bill. But states have a patchwork of regulations that open the door in certain places. The FDA's own Q&A on CBD says: “Is it legal for me to sell CBD products? It depends, among other things, on the intended use of the product and how it is labeled and marketed.”

Various speakers at the hearing Friday urged the FDA to craft regulations to allow marketing but assure people that adequate safety testing is being performed.

“The patchwork of state and local laws confuses consumers,” said Betsy Booren, of the Grocery Manufacturers Association. “We need a consistent federal regulatory framework.”

Academics at the hearing said little was known about CBD and urged caution. Barry Gidal, of the University of Wisconsin, said CBD has a complicated set of effects on people. The effects on patients from the blood-thinner Warfarin, a life-saver for people seeking to avoid strokes, change sharply when the patient took CBD, he said

“We are constantly getting behind the real world, as far as what people are actually taking,” said Igor Grant of the University of California, San Diego. For example, he said, when CBD products are put on people’s skin, “we have no idea if they are absorbed.”

Bill Gurley, from the University of Arkansas, said that on numerous labels his group evaluated, claims varied greatly from the true amount of CBD in the product.

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