

# FDA's rejection of dietary supplement pathway for CBD frustrates industry groups

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The FDA rejected calls to regulate CBD as a dietary supplement — as many industry officials had called for — and instead asked Congress to help it develop a new regulatory pathway for hemp products. | Michael M. Santiago/Getty Images

Cannabis industry officials have been clamoring for FDA guidance on CBD products for years.

On Thursday, the public health agency finally delivered, but it's not exactly the response

industry officials had hoped to receive.

The FDA [rejected calls to regulate CBD as a dietary supplement](#) — as many industry officials had called for — and instead asked Congress to help it develop a new regulatory pathway for hemp products.

While the announcement showed an evolution in the FDA's understanding and approach to hemp, many industry officials viewed it as a setback.

"We ... see no need for FDA to go through the lengthy, burdensome exercise of establishing a new regulatory pathway for CBD, or other hemp-derived cannabinoids," Jonathan Miller, general counsel for the U.S. Hemp Roundtable, said in a statement. "CBD products have been sold at retail for nearly a decade with no significant safety issues."

The Council for Responsible Nutrition — one of three organizations that petitioned the FDA to regulate CBD like dietary supplements — agreed.

FDA's concerns about labeling, preventing contaminants and CBD content limits "can and should be addressed through the existing dietary supplement ... process," CRN CEO [Steve Mister said in a statement](#). "CRN offered the agency a blueprint for that pathway, and it has been ignored."

### **Evolving beyond CBD**

The market for consumer CBD products boomed after the 2018 farm bill legalized hemp. But that growth has been stifled by a lack of FDA guidance on those products, [leading to an oversupply and market bust](#). Without federal regulations, many major retailers sat on the sidelines.

For years, the FDA has pointed to a lack of data on CBD safety to inform federal regulations. But the agency is changing its tune.

"It's not necessarily that we need more data," an FDA official said in an interview, speaking on the condition that they not be named. "What we're proposing here is an alternative framework with alternative safety standards."

The FDA is looking for a separate regulatory pathway that is broader than the existing frameworks for food and dietary supplements. That's in part because there are different form factors for CBD products — from CBD-infused topicals to inhalable products like

vapes and smokable flower. The FDA wants a separate regulatory pathway to be able to include those different products, the official explained.

The agency remains concerned about the long-term safety of CBD products, citing issues like potential harm to the liver, interactions with medications and possible damage to the male reproductive system.

"It appears that CBD is not safe enough to put in foods and dietary supplements," the FDA official said. "What we envision in a new pathway is basic oversight for products ... [including] special labeling requirements [and] CBD content limits."

The FDA is also looking beyond CBD, acknowledging consumer interest in other hemp-derived compounds. Non-intoxicating hemp constituents like CBC, CBN and CBG also need federal oversight, not to mention the "major issue" of intoxicating hemp products like Delta-8 THC, the FDA official said.

But the FDA declined to say whether it plans to work with Congress to address those issues in the 2023 farm bill, where some hemp industry advocates are hoping to take on the burgeoning market for intoxicating cannabinoids marketed as hemp.

At least one key lawmaker expressed frustration on Thursday at the agency's lack of clear guidance addressing hemp-derived products.

"Farmers, producers, and consumers need certainty about when and how CBD is safely included in products," said a spokesperson for Sen. [Jeff Merkley](#) (D-Ore.) in a statement. "Sen. Merkley will continue pushing, because stakeholders need action from FDA, not a plan to wait for Congress. They have the authority they need and should use it."

But Rep. [Chellie Pingree](#) (D-Maine), who sits on the Agriculture Committee and [introduced hemp legislation](#) in the last Congress, said the FDA's announcement shows the need for action by lawmakers.

"After years of pushing FDA to issue CBD regulations, today's announcement affirms the need for Congress to pass legislation and finally provide a regulatory path for CBD," Pingree said in a statement to POLITICO.

### **Hemp industry woes**

While the agency's announcement shows some progress on the issue — moving beyond concerns about data and expanding its scope to include other hemp-derived compounds

— some hemp industry advocates pushed back on the agency's assertions that a separate regulatory pathway is needed.

Miller and Mister criticized the agency for relying on data from pharmaceutical studies on CBD, which tend to have much higher doses than products found on the consumer market. That data does not reliably convey the safety of consumer CBD products, they argued.

Meanwhile, the FDA will continue its enforcement efforts by sending warning letters to CBD producers that pose a danger to public health.

For years, those warning letters were targeted to producers making egregious medical claims, but the agency has expanded enforcement efforts in recent months to include things like form factors that could make it easy for consumers to "accidentally take CBD or excessive amounts of CBD," the FDA official said.

In November, for example, the agency sent [warning letters to CBD beverage manufacturers](#).

Despite the hemp industry's frustrations, some regulatory experts see the FDA action as a helpful step in creating more stability for the CBD market.

"It's a good thing that they're trying to get their hands around it given its prevalence in the marketplace," said Michael Werner, co-leader of Holland & Knight's healthcare & life sciences team. "The other really good development is [the FDA was] as clear as they could be that they want to work with Congress to try to figure out and develop the appropriate pathway."

Werner points out that the agency could have simply reiterated its stance that food and beverages containing CBD aren't legal products under federal law.

"FDA is signaling that they want to figure out how the products can be marketed safely," he said. "They're not saying you can't ever do this."

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