UK: +44 (0)207 989 0813
NA: +1 646 896 3065
AU +61 2 9280 0700
action@proactiveinvestors.com

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# FDA to hold its first public hearing Friday on regulating CBD

CBD-infused products such as lotions, capsules and oils are already widely available in major chain stores such as CVS and online. And the non-intoxicating cannabis component, cannabidiol, is starting to turn up in food and beverages as other companies make plans to get on the CBD bandwagon.

Companies that manufacture and sell CBD products typically market them as a safe and natural way to combat anxiety, inflammation and insomnia. Other vendors, however, are pushing the marketing envelope by touting CBD as some miracle-cure-all for Alzheimer's disease, cancer and ADHD in the face of nonexistent or nebulous research.

But now this unregulated Wild West of sorts in the North American CBD industry, estimated to be worth $16 billion by 2025, could be coming to an end, as the US Food and Drug Administration will hold its first public hearing this Friday on how it should regulate cannabis and CBD.

## CBD industry needs uniform product standards

Regulating the CBD free-for-all, which will come soon via the FDA or Congress, could be a good thing for a fast-growing industry that needs uniform product standards and rules of operation so players can market effectively and legally as well as communicate properly with investors, experts say.

"Regulation enables growth in every successful industry, and we have a once-in-a-lifetime opportunity to create a multibillion-dollar market that meets consumer needs," said Josh Epstein, chief executive of Socati, an Oregon-based processor of broad spectrum hemp extracts.

But guidance is needed on critical matters, especially when it comes to establishing a credible verification process to guarantee product purity, quality manufacturing, and labeling transparency, he said.

"Without that, a race to the bottom is inevitable as irreputable companies continue to pop up, and consumers face harm from products that contain unknown quantities of cannabinoids or products contaminated with pesticides or heavy metals," Epstein said.

## FDA focusing on CBD as a food and beverage ingredient

The FDA is not expected to issue any decisions during what is a information-gathering process, but the agency will have a strong focus on how CBD is marketed and how much CBD should be added to food and drinks (if at all).

The regulator has been under pressure to create a regulatory framework for CBD -- which took a new urgency when Congress make hemp legal in December under the Farm Bill.

The vast majority of CBD is extracted from hemp, which is a cannabis plant that has trace amounts of THC (0.3% or less). THC, or tetrahydrocannabinol, is the psychoactive compound that gets people "high."

CBD was not legalized in the Farm Bill, but rather it was moved under the purview of the FDA, which immediately said

companies cannot add it to food or beverages.

## FDA already issuing warnings over 'snake oil' claims in CBD marketing

The FDA also has sent warning letters to a few CBD companies that have made unsubstantiated health claims for serious ailments. In addition, the agency has expressed concern that allowing CBD in food could dampen incentives for drug makers to conduct research into CBD's health benefits.

In announcing the hearing, then-FDA Commissioner Scott Gottlieb said in a statement that there are "open questions about whether some threshold level of CBD could be allowed in foods without undermining the drug approval process or diminishing commercial incentives for further clinical study of the relevant drug substance."

Industry experts predict that when eventual regulations are adopted, they'll probably allow lower for concentrations of CBD as a food additive and higher concentrations as an approved drug.

Contact the author: patrick@proactiveinvestors.com

Follow him on Twitter @PatrickMGraham

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