FDA Announcement on CBD: We Need Help from Congress

written by Mike Roberto | January 26, 2023

On January 26th, 2023, the **FDA** made a major announcement regarding **CBD** *(Cannabidiol)*, coming after *years* of deliberation, debate, and discussion. The gist of the message:

“We need help from Congress!”

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FDA to Congress: We need more tools!

In a press release titled *"FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward"*,[1] principal deputy commissioner Janet Woodcock stated the following highlights:

> *Today we are announcing that after careful review, the FDA has concluded that a new regulatory pathway for CBD is needed that balances individuals' desire for access to CBD products with the regulatory oversight needed to manage risks. The agency is prepared to work with Congress on this matter. Today, we are also denying three citizen petitions that had asked the agency to conduct rulemaking to allow the marketing of CBD products as dietary supplements.[1]*
>
> *The use of CBD raises various safety concerns, especially with long-term use. Studies have shown the potential for harm to the liver, interactions with certain medications and possible harm to the male reproductive system.*
>
> *— Janet Woodock, FDA*

She references that her team closely examined:

The FDA is requesting help from Congress in order to regulate CBD!

1. Studies related to CBD-based drug *Epidiolex*,[2]
2. Scientific Literature (published up to 2019),[3] and
3. Information submitted to a public docket (with 71 documents and 4,530 comments received).[4]

The FDA doesn't explicitly mention DSHEA 1994, the law that governs the dietary supplement industry.[5] However, the letter states that the existing authorities *"provide only limited tools for managing many of the risks associated with CBD products."* For instance, they seek more evidence to determine how much CBD can be consumed, and for how long, before causing harm.

As such, they're reaching out to the health and wellness experts that are the United States Congress to *"explore potential regulatory pathways"*.

CBD warning letters to come??

Additionally, they close with the following:

> *The FDA will continue to take action against CBD and other cannabis-derived products to protect the public, in coordination with state regulatory partners, when appropriate. We will remain diligent in monitoring the marketplace, identifying products that pose risks and acting within our authorities.[1]*

Could this mean enforcement action is coming?

Dan Fabricant of Natural Products Association Speaks Up

We emailed Dan Fabricant of the NPA (Natural Products Association) for a quote, and received the following:

> *"They really dislike the industry, flat out, that's what this is. Hemp/CBD is a botanical, so there's no framework for a botanical at FDA currently? Interesting. Somehow I remember using those exact tools to regulate other botanicals. FDA now thinks it's the 101st member of the senate or 436th member of the house, they decide on the laws, versus operate them, which is their job by law. The*

> *fact they wouldn't even open a docket to let safety data be provided for notice and comment rulemaking says it all, they aren't interested in safety data no matter how many times they say no data exists. Enough tox data exists for other governments to move ahead. This is solely about not wanting to upset the apple cart on drug exclusion for pharma. I hope none of the other industry groups are misguided and reckless enough to take the bait, 'we'll just give FDA what they want, like MPL and that way we can get CBD done" I can hear certain folks saying it now and it is concerning."*
>
> *— Dan Fabricant, Natural Products Association*

Note that in this statement, Dan is referring back to his time as Director of the Division of Dietary Supplement Programs at the FDA from February 2011 to April 2014.

He also attached a more *official* response from the NPA, a press release titled *"FDA's Dereliction of Duty on CBD Regulation Continues"* and subtitled *"Agency's Latest News Release Shows No Meaningful Progress on Regulatory"*.[6] Inside, it states the following:

> *"Just months after FDA rejected NPA's extraordinary Citizens Petition on a CBD regulatory path and the submission of new scientific data from CBDMD for FDA examination, the agency today claimed it does not have appropriate authority to regulate the popular and widely-used ingredient that continues to proliferate markets across the country.*
>
> *This is an astonishing dereliction of duty, especially compared to the agility and professionalism the agency showed it was capable of during the pandemic. After more than a decade of promises, hearings, data sharing, market proliferation, and states filling the regulatory vacuum, the FDA's Dietary Supplement Division claims it cannot do what Congress authorized, which is to regulate dietary supplements under the law," said Daniel Fabricant, Ph.D., President, and CEO of the Natural Products Association.*
>
> *But it gets scarier. When you read between the lines of today's FDA statement, the agency appears to be saying that*

> *it would prefer to defy and attack DSHEA and develop different regulatory paths for ingredients at its own discretion. That could include requiring premarket approval, unnecessary testing, or who knows what. That is an especially dangerous precedent not only for CBD but for the entire natural products industry and ingredients like hemp that clearly fall under the agency's jurisdiction. We couldn't be more disappointed and will look for relief with every branch of government and will need the help of our members to right the wrong."*
>
> *— Natural Products Association[6]*

CBD, NAC, and NMN…

There is a *lot* of regulatory back-and-forth underway, as the natural products industries have been battling the FDA over drug exclusion provisions in DSHEA 1994.

This advertisement from 1993 is proof that NAC was sold as a dietary supplement *before* 1994,[7] and should be a legal dietary supplement ingredient.[8] Why did FDA go after it all of the sudden in 2020 of all years, and can we trust them with future decisions?

One such case is with **NAC** *(N-Acetyl Cysteine)*. This is an extraordinarily safe and well-tested ingredient that the FDA attempted to exclude from the definition of a dietary supplement through some suspiciously-timed 2020 warning letters sent to brands selling hangover products, in which the agency said it was a prescription drug in 1963, exempting it from status as a dietary supplement.[9-12] However, it was also sold as a dietary supplement before 1994,[7,8] and the prescription wasn't for oral use anyway.

The NPA sued the FDA,[7,8,13] forcing the FDA to back off and issue a final guidance exercising "enforcement discretion", ultimately allowing NAC-containing supplements to be legally sold if all manufacturing and labeling laws are followed.[14-16]

The whole story on NMN is on PricePlow

The other case involves **the FDA's attack on NMN** *(nicotinamide mononucleotide)*, a case we'll keep up-to-date through its conclusion.

Ultimately, we are told that *"all roads lead to CBD"* – the FDA seems very adamant about *not* allowing natural ingredients to serve as both dietary supplements (to supplement the diet by increasing the total dietary intake) *and* prescription drugs (with specific health claims).

These will be ongoing matters, and you can sign up for our alerts on these topics so that you're notified when new articles or videos are published.

Update: FDA Issues Responses to Citizen Petitions

Update on January 31, 2023: For those following this topic, it's worth reading the FDA's responses to three citizens petitions (to Consumer Healthcare Products Association, Council for Responsible Nutrition, and Natural Products Association). They're linked to Regulations.gov from a page on FDA.gov.[17]

In response to this, a comment was made on LinkedIn by Bruce Kneller, who adds a contrarian point to the arguments of the trade organizations listed above:

> *While certain lobbyists might not like FDA's position in this release? I think they are fairly clear here: They do not view CBD as a dietary ingredient/supplement & are basically "punting" to Congress to create a new/separate statute or set of laws to carve out how (if?) CBD containing products can be marketed & sold to the general public. My guess & nothing more is that what is "needed" is something a bit like what governs the sale of OTC drugs. Per the current statutes, I can't see how CBD is a dietary ingredient/supplement since it's already an Rx drug (IND &*

> *NDA filed & accepted) with substantial public clinical investigation. So that does put FDA in a pickle. Congress should write & codify exactly "what" they think CBD is (aside from a drug) & find a reasonable path to allow access/sale. Congress. Not FDA.*
>
> *— Bruce Kneller[18]*

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