Nutrition INDUSTRY EXECUTIVE

CRNUpdate

Will CBD Become a Shakespearean Tragedy?

By Steve Mister, president & CEO, CRN

To CBD or not to CBD, that is the question ...

Shakespeare posed plenty of contemplative questions, but for today's dietary supplement marketers, retailers and consumers, perhaps nothing is more pressing than—nor as confusing as—the decision whether to jump into the cannabidiol (CBD) market—or not.

No ingredient in recent memory has attracted the level of buzz that CBD has. By some estimates, the over-the-counter market for hemp-derived food, supplement and personal care products containing CBD exceeded $190 million last year, and is projected to surpass $650 million in five years. It has been added to everything from pills and powders to gummies, from snacks and teas to toothpaste and lotions. All this while the ingredient was arguably still illegal under both the Controlled Substances Act and the Food, Drug & Cosmetic Act.

So the passage of the 2018 Farm Bill is welcome news to would-be marketers looking for some clarity as to the legal status of CBD. The inclusion of the Hemp Farm Act in the final legislation removed hemp from the definition of marijuana, which is a Schedule 1 controlled substance, provided the plant contains not more than .3 percent THC (the pyscho-active substance that gives marijuana its "high"). By effectively taking hemp, and products derived from the plant, off the federal controlled substances list, the Farm Bill allows for legal cultivation, harvest, transport, marketing and research of hemp and its constituent CBD, and it eliminated a significant legal barrier to lawful marketing of CBD-containing products.

CBD Restraints

But not so fast. While the DEA (Drug Enforcement Administration) issues have been addressed, FDA (U.S. Food and Drug Administration) has not given CBD the green light for inclusion of CBD in food and dietary supplements, and that hurdle may be just as formidable. FDA's issues with CBD are unrelated to the ingredient's connections to marijuana and are multifaceted. Roadblocks still exist for lawful marketing of CBD as either a food or a dietary supplement.

First and foremost, FDA has repeatedly opined that it believes CBD does not meet the definition of either a "dietary supplement" or a "food" because of an exclusion buried in the definitions of both terms in the federal Food Drug & Cosmetic Act. That law excludes from those definitions any "article" that was previously studied as a drug in a substantial clinical investigation prior to it being marketed in one of those categories.

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This provision first appeared in DSHEA (Dietary Supplement Health and Education Act of 1994), and was later replicated for "food," to provide pharmaceutical companies with exclusive use of compounds for which they had invested research before they were marketed as supplements or food. In other words, the law provides that if researchers get interested in a compound for potential drug purposes after it is already marketed as a food or supplement, the drug and the supplement must coexist in the marketplace together (think omega-3s or niacin), but if the drug research comes first, then the pharmaceutical gets the monopoly and the article doesn't qualify as a food or supplement. This provision is the crux of the litigation from the 1990s involving red yeast rice, and why today supplement manufacturers are prohibited from standardizing the levels of lovastatin in those products.

FDA has invoked this obscure provision (found in 21 USC §321(ff)(3)(b), if you want to go look for yourself) in a series of warning letters over the past year with the perspective that CBD was first studied for its eventual use in the drug Epidiolex before it was lawfully sold in a food or supplement. At CRN's conference in October, FDA's Director of Dietary Supplement Programs (ODSP) Steven Tave stated emphatically from the podium that FDA believes the "clinical investigation" clause precludes lawful marketing of CBD in either supplements or food.

Fortunately, an escape hatch exists. The statute also permits FDA to exempt a particular article from the exclusion on marketing as a food or supplement if FDA, in its discretion, "issues a regulation, after notice and comment, finding that the article would be lawful ... " And there are some compelling public health reasons why FDA could be motivated to use this provision to make an exception for CBD.

As I mentioned earlier, the proverbial horse is already out of the barn when it comes to CBD. The market for CBD products—legal or not—is exploding. Despite warning letters and podium policy, consumers are demanding access to CBD and marketers are already responding with $190 million of products. So FDA faces a choice: continue to rail at the wind without the enforcement resources to put the horse back into the barn, or devise another way to regulate CBD. Allowing the sale of food and supplements containing CBD would permit FDA to impose GMPs, mandatory adverse event reporting, notification of claims, access to safety data and other regulatory requirements onto the sector. FDA could determine that, in the interest of public safety, an exception to the clinical investigation clause is both expedient and justified for CBD.

Claims and Safety Concerns

FDA has also expressed concerns about CBD products that claim to prevent, treat, cure and mitigate diseases. Such claims are limited to drugs. CBD marketers should be especially cautious not to make drug-like claims for their products because doing so could turn even otherwise lawful CBD products into unapproved new drugs.

But there's another reason to be conservative in marketing claims: the publicly available research on the benefits of CBD reveals that the science behind

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this compound is still in its infancy. Without sound clinical research supporting the promoted health benefits, marketers are vulnerable to investigations of their claims and whether they meet the "competent and reliable scientific evidence" standard, the long-established threshold for advertising claims at the Federal Trade Commission. In fact, a review of recent FDA warning letters espousing objections to CBD on definitional grounds suggests that drug-like claims for the products may have triggered the closer scrutiny by FDA in the first place.

Lastly, and perhaps most critical, are the potential safety concerns for CBD. A review of the extensive precautions and warnings in the drug labeling of Epidiolex indicates that at higher dosages, safety issues may exist. Would-be CBD marketers should remember that FDA's position that CBD was not marketed as a supplement prior to the clinical trials of CBD as a drug, inherently reveal FDA's view that CBD was not on the market prior to 1994, and thus, it qualifies as a new dietary ingredient.

That triggers an obligation to submit a New Dietary Ingredient (NDI) notification to the agency complete with evidence why the marketer believes it is reasonably expected to be safe. So firms should already be developing their safety dossiers on their method of manufacturing CBD and preparing these submissions for when the other issues have been resolved. Alternatively, companies could decide to assemble their own panel of experts and develop a self-affirmed GRAS (generally recognized as safe) certification, as one prominent marketer has already done, but that takes time and planning too. Either avenue underscores the need to demonstrate that each unique CBD offering is safe for consumers.

So the journey toward getting lawful CBD products to the supplement and food marketplace has begun, but additional obstacles still lie ahead. Passage of the Farm Bill was a critical first step, but it doesn't address these other issues. Industry will need to work collectively through the trade associations to address FDA's concerns.

If we do, the market for CBD could bloom like Juliet's rose to smell as sweet and flourish to its full potential. Otherwise, this could become the winter of our discontent. And CBD, by any other name, will still be a missed opportunity.

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