

Cosmetics Firms ‘Chomping At The Bit’ To Use CBD, But Do So At Own Peril, Attorney Says

► By Ryan Nelson

TUCKER ELLIS ATTORNEY RONIE SCHMELZ DISCUSSES uncertainties companies face in marketing CBD-containing cosmetics and measures they can take to mitigate risks ahead of expected regulatory guidance.

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The 2018 farm bill removed hemp from Schedule 1 of the Controlled Substances Act, legalizing its licensed production nationwide as well as interstate transport of the herb and derivatives thereof.

There’s a catch though.

The legislation, formally the Agriculture Improvement Act of 2018, tasked the US Department of Agriculture with developing regulations to implement the act’s provisions and promote uniformity in state oversight programs, which must be USDA-approved.

USDA aims to publish those regulations in fall 2019 to accommodate the 2020 planting season.

In a May 1 interview, Ronie Schmelz, an attorney in Tucker Ellis LLP’s Los Angeles office with more than 25 years of litigation-defense experience, said that until USDA’s regs issue, the 2014 farm bill is the controlling statute.

That legislation authorized government and academic hemp research programs in states that had legalized the plant’s production. The bill’s passage represented a significant shift in federal attitudes regarding cannabis and its potential medicinal virtues, but did not dramatically alter commercial hemp prospects or clear the way for hemp’s transport across state lines.



Schmelz is advising clients to reach contractual terms with suppliers that provide them with “soil to serum” visibility, including a clear understanding of ingredients’ origin (from a licensed grower?) and chemical makeup (no more than 0.3% THC?).

In comparison, the 2018 farm bill is a game changer that has triggered – if prematurely – a boom in hemp cultivation, research and commercial activities.

“We have many clients who are chomping at the bit, and have been for a while, to put CBD in their cosmetic products,” Schmelz said.

She continued, “What’s interesting is that after the farm bill passed, everybody just assumed it is now legal to put CBD in products and there’s no problem marketing them across the US. In fact, that’s not the case and it’s



much more complicated than that. I don't think companies appreciate the risks that are still involved in marketing products containing CBD."

The attorney pointed out that the 2018 farm bill is silent on the issue of product sales.

"You have to determine whether or not each state will permit you to sell these products," Schmelz said, noting that states where cannabis has been legalized for medicinal and/or recreational purposes are bound to be friendlier than others.

Retailers may take some of the due diligence off vendors' shoulders. Walgreens told CNBC in late March that it would begin selling topical CBD products in 1,500 stores in selected states, including Oregon, Colorado and Vermont, weeks after rival CVS revealed that it is taking a similar approach.

However, the news sent former US Food and Drug Administration Commissioner Scott Gottlieb to Twitter to express concerns about national pharmacy chains foraging into CBD product sales.

"We'll be contacting them to remind them of #FDA obligations and our commitment to protect consumers against products that can put them at risk," he tweeted April 2.

Interstate shipping of products to retailers or end users also could be a risk for companies until USDA clarifies the situation. At the moment, confusion about the new law has resulted in truckers being charged with felony drug trafficking when hauling purported hemp between supply chain links in different states.

Hemp is defined by the 2018 farm bill as the *Cannabis sativa L.* plant and any of its parts with no more than 0.3%, on a dry weight basis, of delta-9 tetrahydrocannabinol (THC), the main psychoactive constituent in cannabis.

Because hemp is indistinguishable at a glance from higher-THC strains of the plant that still constitute marijuana under the CSA, its wider-scale cultivation and transport poses considerable challenges for law enforcement.

Officials could face similar challenges, without the bene-

fit of sophisticated lab equipment, when confronted with cosmetics containing CBD or other hemp ingredients.

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The attorney suggested that firms marketing CBD-containing cosmetics could run into problems if local authorities or other interested parties were to test their products and detect excessive THC levels in addition to CBD, or no trace of CBD at all.

"You want a representation and warranty that you can actually rely on and hold [suppliers] responsible" as needed, Schmelz said.

Companies also should explore whether they are insured against possible issues that could arise from use of CBD and other hemp components in today's highly uncertain legal and regulatory climate.

"There's still reason to be excited about the fact that the farm bill was enacted, but companies should not be lulled into thinking that passage of the bill threw the doors wide open to being able to market anything CBD," Schmelz said.

She noted industry frustrations. "My clients say, 'When I go online, I see it everywhere. Everybody's selling CBD products.' I tell them the fact that companies are selling the products does not mean doing so is legal or that the companies do so without any legal exposure. The landscape remains unsettled and companies that enter the market at this stage do so at their own peril. At the end of the day, companies need to assess their risk appetite and determine whether and how to enter this nascent industry."

Drug Claims Clearly Off-Limits, Per Usual

There's no denying that demand for CBD and other cannabis-derived products is soaring.

Unilever PLC's Schmidt's Naturals brand reportedly has a CBD-based skin-care line in the works. Other industry

leaders, such as **Estee Lauder Companies Inc.**, are taking a more cautious approach, starting with hemp seed oil – which is generally recognized as safe for use in food products – as opposed to the more contentious CBD. (Also see “*Lauder/Origins’ Hello, Calm Mask: Gateway To Bigger Cannabis Skin-Care Play?*” - *HBW Insight*, 18 Sep, 2018.)

FDA has made known its position on foods and dietary supplements containing CBD, essentially declaring them in violation of federal law while exercising enforcement discretion at present by focusing on products carrying disease-treatment and other drug claims. (Also see “*FDA Opens CBD Regulatory Path Docket, Warns Firms On Claims Missteps*” - *HBW Insight*, 2 Apr, 2019.)

The agency’s stance on CBD in cosmetics is less clear.

“What’s absolutely certain is that companies can’t say anything about CBD that would convert their product from a cosmetic to a drug,” Schmelz said.

That would include highlighting CBD’s oft-cited anti-inflammatory benefits. FDA has identified anti-inflammatory statements as unapproved drug claims in previous

warning letters to cosmetics manufacturers.

Personal-care companies also must be certain to substantiate CBD products’ safety, as required for all cosmetics on the US market. FDA has asked the Cosmetic Ingredient Review to prioritize CBD’s safety assessment, though CIR says not one CBD-containing cosmetic has been reported voluntarily to FDA to date. (Also see “*FDA Proposes Priorities For Cosmetic Ingredient Review: Mica, Probiotics, CBD*” - *HBW Insight*, 18 Apr, 2019.)

FDA will be holding a public hearing May 31 to gather information on products containing cannabis or cannabis-derived compounds, such as CBD.

The agency also is accepting comments on the topic through July 2, with 468 comments received as of May 2.

Schmelz noted that she will be attending the FDA hearing and invites stakeholders to contact her about concerns or questions they have that could be put to the agency at that time.

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