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Making Hemp Lawful As Dietary Ingredient In US Could Be More Than Marketers Bargain For

by Malcolm Spicer

Marketers of supplements containing hemp-derived cannabinoids aren't particularly proficient at meeting FDA's regulatory requirements, says Rodney Butt of consultancy Nutrasource Pharmaceutical and Nutraceutical Services.

Making the use of hemp as dietary ingredients lawful in the US doesn't look promising, which could be best for some firms already marketing the products because becoming fully compliant with federal regulations could be beyond their capabilities.

Marketers of supplements containing hemp-derived cannabinoids aren't particularly proficient at meeting the Food and Drug Administration's regulatory requirements for manufacturing and marketing their products, said Rodney Butt of Canadian consultancy Nutrasource Pharmaceutical and Nutraceutical Services Inc. at a recent Food and Drug Institute conference.

Take compiling adverse event reports and submitting reports of serious events to the FDA within 15 days of receiving the information, for instance. It's not a strong point across the supplement sector, said Butt, Guelph, ON-based Nutrasource's senior vice president for strategic solutions.

"One of the challenges has always been within the dietary supplement world that I've always found, safety reporting has been a weak link in all companies associated with dietary supplements," he said.

"It's something they know they have to do, it's something they tend to find third-party vendors to help them out with, but it's there in the in the law."

Others on the panel discussing the potential for FDA's regulation of hemp weren't confident the

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current marketplace status – sales allowed through tacit enforcement discretion – is going to change anytime soon *(see related story)*.

'Buried In Data' On Adverse Events

Like firms using other ingredients, some hemp supplement marketers are appropriately compiling information from adverse event reports submitted by consumers, health care providers or other parties. What they do with the data, though, is the problem, Butt says.

"They get buried, basically buried in data," he said, adding, "How do you deal with this mountain of information that's coming out?"

He noted work he'd done involving a firm's 1,223 adverse event reports for a supplement, including 48% for gastrointestinal disorders.

However, "they have no adverse events" because the product is labeled with directions to take with food, Butt said.

"Instead, go to changing the labeling, and put it more clearly on the label, take with food. The same thing's going to come forward in cannabis and cannabinoids because there's a 100% absorption impact with taking it with food."

US Hemp Product Industry 'Dying On Vine' Without Lawful Use Legislation Or Enforcement Guidance

By Malcolm Spicer

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FDA's tolerance of sales of hemp-containing supplements isn't the assurance industry needs for investing in development of ingredients and products which have been shown to provide various health benefits.

Read the full article here

Hemp In Drugs Sets FDA Safety Expectations

With a dearth of safety information on using hemp ingredients in food, supplements and non-drug topicals, the FDA is particularly interested in adverse event reports for cannabidiol and other cannabinoids.

The agency's attention, Butt said, was piqued for hemp- and cannabis-related adverse events before supplements, and to a lesser extent food and topicals, containing the ingredients became widely available in the US.

"The FDA is really tuned into unexpected and serious side effects. If CBD or any cannabinoids became a dietary supplement, the FDA is already aware of the prescription drug-associated adverse events," he said.

Even though the FDA is "dying right now for safety

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RODNEY BUTT: "IF CBD OR ANY CANNABINOIDS BECAME A DIETARY SUPPLEMENT, THE FDA IS ALREADY AWARE OF THE PRESCRIPTION DRUG-ASSOCIATED ADVERSE EVENTS." *Source: Source: FDLI*

and information" on hemp and cannabis, the agency has developed safety profiles for ingredients extracted from the plants based on applications for investigational new drug programs and on new drug applications, Butt added.

On the other hand, little if any data or other information submitted to the agency in new dietary ingredient notifications or in generally regarded as safe submissions is available to help establish hemp as safe for use in supplements for food.

The safety profiles from drug applications and the lack of safety information from NDINs and GRAS proposals, he said, would go a long way toward hemp ingredients remaining unlawful for use in dietary supplements and available only as long as the FDA allows through enforcement discretion.

"The profile is very clear at the FDA perspective what to look for. But secondly, and more importantly, which a lot of the dietary supplement companies don't understand, is an NDIN or a [GRAS notice] does not meet the standards that the FDA are going to be looking for about reporting safety because they've got a safety profile that they're looking for," Butt said.

The drug ingredient profiles reveal interactions between active pharmaceutical ingredients as well as an ingredient's reaction with a disease or condition. That type of information isn't known for hemp as a dietary ingredient.

"These are types of safety data the FDA already knows, which makes them approving CBD as a dietary supplement challenging," Butt said.

The comparative wealth of information available about using hemp and cannabis ingredients in pharmaceutical products, much more than about other substances derived from botanicals, puts cannabinoids at a particular disadvantage for lawful use in supplements, he added.

"Really the key issue here, from my perspective, is that for the FDA, CBD is a unique product the FDA already understands. … they're going to be looking at it from a safety perspective differently than any other" consumer health products, Butt said.

Under FDA regulations, because hemp- and cannabis-derived ingredients are approved for use in

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drugs available in the US, they are unlawful for use in non-drug products subject to its oversight. Since opening a docket in 2019 for comment on the safety of using hemp and cannabis ingredients in non-drug products, the agency has allowed, through a de facto enforcement discretion policy, sales of supplements, food and personal care products marketed in compliance with regulations relevant to each category. (Also see "*With Data Coming Slowly On Cannabis, Hemp Ingredients, FDA Launches 'Acceleration Plan'*" - HBW Insight, 8 Dec, 2021.)

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