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Q & A: WHAT DOES THE 2018 FARM BILL MEAN FOR CBD SUPPLEMENTS?

By: Phil Nash, Esq. and Rick Collins, Esq.

On December 20, 2018, President Trump signed into law the 2018 Farm Bill, changing the landscape for companies in the Hemp industry. However, companies seeking to market and sell products containing Cannabidiol (CBD), a chemical compound derived from the cannabis plant (which includes both Hemp and Marijuana), need to know what the new Farm Bill says and what it doesn't say. While the landscape is fluid and still evolving, here are our current thoughts.

Q: What's the difference between the 2014 Farm Bill and the 2018 Farm Bill?

A: The first major difference is the way that "Hemp" is defined (note that the 2014 Farm Bill used the term "Industrial Hemp" while the 2018 Farm Bill simply uses "Hemp"). The 2018 Farm Bill presents a broader definition of Hemp that includes the specific parts of the plant and "all derivatives, extracts, cannabinoids, isomers... etc." Under the 2014 Farm Bill, the only parts of the Hemp plant that were permitted to be grown and cultivated were those parts that were specifically excluded as a controlled substance from the federal Controlled Substances Act (CSA) – "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." The 2018 Farm Bill specifically amends the CSA to exempt "Hemp" from the definition of "marihuana" and, as a result, Hemp is no longer a controlled substance. That amendment removes Hemp, as it is defined in the new Farm Bill, from the oversight authority of the Drug Enforcement Administration (DEA).

Q: Are THC levels still important?

A: Yes, the definition of Hemp requires a THC limit of "not more than 0.3 percent on a dry weight basis." The 2018 Farm Bill amends Schedule I of the CSA to exclude THC that comes from Hemp (0.3 percent or less). However, a cannabis product with THC above 0.3 percent is not "Hemp" and therefore not exempt from the CSA (it's still a controlled substance).

Q: What does the new Farm Bill say about CBD specifically?

A: The 2018 Farm Bill states that CBD that is derived from Hemp is excluded from the CSA. As a result, CBD that is extracted from Hemp

is no longer a scheduled substance, meaning that the DEA cannot take action against the possession, transport, or sale of CBD that is derived from Hemp.

Q: Does the 2018 Farm Bill definitively take away the DEA's authority over CBD?

A: Yes and no. As stated above, the 2018 Farm Bill removed CBD that is derived from Hemp from the CSA, thus removing DEA from the equation. However, CBD can also be extracted from Marijuana, which remains a Schedule I controlled substance, so the DEA still has authority over CBD extracted from Marijuana.



Q: Does the new Farm Bill allow CBD to be lawfully sold as a dietary supplement?

A: Contrary to some claims, the answer is still NO. The 2018 Farm Bill does not affect the regulatory status of CBD as a dietary supplement, food, or cosmetic. Dietary supplements are regulated by the FDA under the Food, Drug and Cosmetic Act (FDCA). The FDA has made clear that it is of the opinion that CBD is not a permissible dietary ingredient, dietary supplement, or food additive.

In fact, the 2018 Farm Bill specifically states that it does not affect or modify the FDCA. As the regulatory agency responsible for dietary supplements, the FDA has the ultimate say when it comes to selling CBD as a supplement, and the FDA has not changed its position that CBD is not a lawful dietary supplement.

Q: Does the new bill change the effect of making claims about CBD products?

A: No. The FDA, along with the Federal Trade Commission (FTC), regulate marketing and advertising, including claims, made about all products sold as dietary supplements in the United States. The FDA and FTC require that all marketing and advertisements made about any dietary supplement be truthful and not misleading and that all claims must be "substantiated." The standard for adequate substantiation is "competent and reliable scientific evidence." Nothing in the new Farm Bill changes the standards for substantiation. Additionally, dietary supplements are prohibited from making claims about their ability to "diagnose, treat, cure, or prevent" any disease.

Q: What would be needed for CBD to be a legal dietary supplement in all 50 states?

A: In order for CBD to be lawfully sold as a dietary supplement under

federal law in the United States, the FDA would need to enact a regulation or issue a guidance about CBD. The FDA has hinted at this possibility, but for now, the FDA considers CBD and products containing CBD which are labeled as dietary supplements to be misbranded and adulterated drugs. Up until this point, we have seen FDA's actions against CBD products focused on those companies that are making impermissible claims that their product can treat, cure, prevent or mitigate diseases and those products whose labeling is not compliant. Also, individual states' controlled substance laws may impact the legality of CBD on a state-by-state basis.

athlete's system builds up to detectable levels. There are also concerns about insurance coverage, banking, and potential threats from plaintiff class action lawyers or claims under the Lanham Act or similar state laws for unfair competition.

While the CBD market is undergoing explosive expansion, there are significant risks. Companies considering adding CBD products to their line should consult with counsel before launch. Should you have any questions about Hemp or CBD, give our law firm a call at 516-294-0300.

Q: Are there other risks in marketing CBD products?

A: Yes. For example, adding CBD to sports nutrition products could result in failed doping tests by drug-tested athletes if the THC in the

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WHAT SERVICES DOES CGMB OFFER?

With the FDA and FTC recently announcing a renewed effort to enforce current regulations in the dietary supplement industry, and FDA's plan to overhaul oversight of dietary supplements (the first overhaul in dietary supplement regulation and oversight in more than 25 years), it is more critical than ever for supplement companies to ensure that all materials are in full compliance with the most current regulations. Could you survive an investigation of your products, your labels, or your advertising copy? How do you navigate the maze of new regulations ... and run your business at the same time? With FDA policies actively evolving, how can you bring a New Dietary Ingredient to market in compliance with DSHEA? How can you ensure your advertising complies with FTC regulations? What must you do in order to comply with the dietary supplement cGMPs?

Collins Gann McCloskey & Barry PLLC (CGMB), is a law firm dedicated to helping clients in the health, fitness and nutrition communities. With recognized experts in sports performance supplements and regulatory, advertising and marketing law, CGMB offers a powerful bi-coastal team providing a variety of legal services to a whole range of companies from start-ups to established organizations. CGMB offers in-depth experience and personalized attention you can trust to get you the answers you need ... when you need them. The partners of CGMB have been formally rated by the professional legal community as practicing at the highest levels of skill and ethical integrity (AV-rated in Martindale-Hubbell). CGMB can help you stay ahead of the curve.

- Are all your product names and intellectual property protected?
- Have your product labels been reviewed by legal counsel?
- Do you have proper licensing and manufacturing agreements in place?
- Are you covered by adequate indemnification agreements?
- Are all your ingredients DSHEA-compliant?
- How can you bring a New Dietary Ingredient to market or obtain GRAS status?
- Do you have SOPs for recording and reporting Serious Adverse Events?
- How can you substantiate your claims to satisfy FDA, FTC, and other federal and state regulatory agencies?
- Do you have proper insurance coverage and SOPs for customer complaints?
- Have you received a Civil Investigative Demand from the FTC?
- Have you been served with a Class Action suit? How would you handle one?
- Could you survive a 483 inspection?
- Could you survive an investigation of your facility, products, labels or claims?
- Are you fully compliant with cGMPs?

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Rick Collins, Esq., is based in New York and provides advice to some of the top names in the sports nutrition industry, and is the legal advisor to the International Society of Sports Nutrition and the International Federation of BodyBuilders. He has defended dietary supplement and sports nutrition companies against claims by FDA and DEA. He is admitted to practice in the courts of New York, Massachusetts, Pennsylvania, Texas and the District of Columbia, and in numerous federal courts.



Philip Nash, Esq., is an associate attorney at Collins Gann McCloskey & Barry PLLC, concentrating his practice in the areas of dietary supplement law and criminal defense. Phil focuses his work within the dietary supplement industry on label reviews, claims reviews, website reviews and FDA and FTC compliance. He regularly advises clients regarding the expanding market of Cannabidiol (CBD) and hemp oil.



Alan Feldstein, Esq., an attorney based in Los Angeles and admitted to practice in California, serves Of Counsel to CGMB. He has extensive experience with contracts, copyright and trademarks, label and advertising review, supplement fact panel review, claims substantiation and assorted regulatory issues. He brings with him over 25 years of advertising and marketing law experience.



Ellie R. Sladic, Paralegal, provides support to the attorneys of Collins Gann McCloskey & Barry PLLC and works extensively with dietary supplement trademark matters. She is a Highest Distinction graduate from Suffolk County Community College's ABA approved A.A.S. Paralegal Studies program, attending on a full academic scholarship. Ms. Sladic is a member of the National Association of Paralegal

Assistants (NALA).

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