

Are CBD Products Really Legal?

Over the past year, hemp products have been springing up everywhere, both online and in retail outlets. Of particular interest to those who market consumer products are foods, supplements and cosmetics with cannabidiol, or CBD, in them. Many assert that such products are all now legal. But is that really true?

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Impact of 2018 Farm Bill.

With the passage of the 2018 Farm Bill, products made from hemp (defined as cannabis sativa L. with a THC content of below 0.3%) became legal throughout the U.S. As a result, there has been an explosion of hemp products in the marketplace, the popular of which are products with CBD. Salves, gummies, tinctures, beverages and all manner of other consumer products are being marketed with CBD, often with fairly extravagant claims about what CBD can do for you and your health.

FDA Issues.

But, while hemp products in general are now legal, products that fall under the jurisdiction of the Food and Drug Administration (FDA) still must meet its regulatory requirements. And that is the problem for foods and supplements with CBD. At this time, the FDA has taken the position that CBD is not a legal ingredient in any food or supplement product. Its reasons for that are technical, and many disagree with the agency's position. Nonetheless, that is the current position of the FDA and, therefore, making and selling foods and supplements with CBD carries with it some risk that the FDA will claim that your products are adulterated and illegal.

Cosmetics fall under a different set of regulations, and the use of CBD in cosmetics is not a problem as long as the manufacturer has evidence that CBD is safe for its intended use in the cosmetic.

Need to avoid drug claims.

At the same time, though, the FDA is well aware of the public demand for CBD products and, for now, is not being too aggressive in pursuing those making and selling CBD foods and supplements.

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There is a very important exception to that, however. If you are marketing your CBD foods and supplements with claims that the use of CBD can help to prevent, cure, treat or mitigate the effects of a disease or illness (i.e., drug claims), there is a much higher chance that the FDA will object to your products and send you a warning letter requiring you to desist.

The FDA regards such claims for any product that has not been gone through the FDA's drug approval process as illegal and the product for which the claims are made as an illegal drug, and it will take action against such products. And, while the use of CBD in cosmetics is legal, making drug claims for such cosmetics is also impermissible and could subject such products to regulatory action. A number of warning letters have been sent to manufacturers over the past several years, some of them leaders in the CBD marketplace.

State law concerns.

Even if no drug claims are made on your products, there are several states that have taken the position that any food and/or supplement product with CBD will be illegal for sale in that state unless and until the FDA approves CBD as an ingredient. The following states have (or have indicated an intention to promulgate) such restrictive rules or announcements:

- California
- Georgia
- Hawaii
- Iowa
- Louisiana
- Massachusetts
- Michigan
- Maryland
- New Hampshire
- North Carolina
- South Carolina

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And other states may join them or be considering such rules. Also, many of the states have their own labeling requirements in addition to federal food and supplement label rules. It is, therefore, advisable to consult with counsel before deciding on whether to distribute your CBD food or supplement product in any particular state to understand both that state's labeling requirements and any risks that may exist in selling your products in that state.

Pathway to legality?

The FDA has stated that it would like to find a pathway to permit the appropriate use of CBD in foods and supplements. The FDA has already had a hearing on this and has solicited more information from manufacturers on CBD and its effects. There is also pressure on the FDA from Congress to find that pathway and to do it sooner rather than later. It remains to be seen, however, if or when the FDA will move forward with action on clarifying the regulatory status of CBD.

What is one to do in the meantime?

There is some reason for hope that the legal bind that makers and sellers of foods and supplements with CBD now find themselves in will be resolved and that regulatory guidance on what is and what is not permissible will be provided. But we can't know how long that will take. For the present, anyone making or selling CBD foods and supplements must understand that their products are at some risk of enforcement action, either at the state or federal levels.

More importantly, if you are making drug claims about your products (including cosmetics), your risk of an enforcement action is much greater. To manage those risks, it is important that you ensure that your products meet all applicable labeling requirements and that any claims you are making for the products be reviewed by experienced legal counsel to avoid anything that might be considered by the FDA to be a drug claim.

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marketing of hemp products and the issues related to the use of CBD in FDA-regulated products. For more information on this topic, please feel free to contact Steve at sellcessor@fbtlaw.com.

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