FDA Refuses to Approve CBD As a Food Ingredient or Supplement

The federal Food & Drug Administration ("FDA") has refused to consider an application by Charlotte's Web Holdings, Inc. ("Charlotte's Web") for a CBD product to be sold as a dietary ingredient. Instead of clarifying the uncertain legal environment around of the sale of CBD products intended for human and animal ingestion, the FDA's inaction maintains the uncertainty.

The federal Food, Dug, and Cosmetic Act (the "FD&C Act") requires that manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" ("NDI") notify the FDA about these ingredients at least 75 days before the NDI or the product containing the NDI is sold in interstate commerce. The notification also must include information and evidence on which the manufacturer or distributor has based its conclusion that a dietary supplement containing the NDI will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. Under the FD&C Act, the supplement containing the NDI is deemed to be "adulterated" unless there is a history of use or other evidence that the NDI, if used as recommended or suggested in the labeling, will reasonably be expected to be safe.

Charlotte's Web submitted a notification to the FDA that it intended to market a NDI, namely a full-spectrum hemp extract in a dietary supplement tincture. Under the FDA rules, Charlotte's Web also submitted information regarding the conditions of use, reports of safety studies, and other information that led them to conclude that the dietary supplement containing the tincture was reasonably expected to be safe.

The FDA responded that the hemp extract cannot be used in dietary supplements because the term "dietary supplement" excludes items or ingredients that have been approved as a new drug under the FDA regulations, and also excludes items or ingredients authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, in both cases unless the item was marketed as a dietary supplement or a food before such approval. The FDA advised Charlotte's Web that its proposed product was excluded from the definition of "dietary supplement" on both counts. CBD is the active ingredient in the drug Epidiolex, which has been approved for certain epilepsy treatments. In addition, the existence of substantial clinical investigations involving CBD has been made public. The FDA further determined that CBD was not marketed as a dietary supplement or conventional food before it was authorized for investigation as a new drug. As a result, the FDA concluded that Charlotte's Web's product could not be marketed as or in a "dietary supplement".

The FDA response went on to advise Charlotte's Web that, even if the product were not excluded from the definition of a "dietary supplement," the FDA had questions about the evidence Charlotte's Web had submitted. In particular, the response expressed concerns about the evidence of history of use, the adequacy of underlying data contained in other studies cited by Charlotte's Web, and the lack of evidence on hepatotoxicity and reproductive toxicity.

The FDA's continued refusal to take action to regulate CBD products for human and animal consumption leaves the entire industry in a legal grey area and continues to cause confusion in the marketplace as to the legal status of CBD products. There is legislation pending in Congress that would instruct the FDA to regulate hemp-derived CBD like all other new dietary ingredients, foods, and beverages.

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