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TTB Industry Circular

Hemp Ingredients in Alcohol Beverage Formulas

To: Proprietors of Bonded Wineries, Bonded Wine Cellars, Taxpaid Wine Bottling Houses, Beverage Distilled Spirits Plants, Breweries, Importers, and Others Concerned

Since the Agriculture Improvement Act of 2018 (the 2018 Farm Bill) excluded “hemp” from the definition of marijuana under the Controlled Substances Act (CSA), TTB has received many inquiries from industry members about whether they may produce alcohol beverages containing ingredients, such as cannabidiol (CBD), derived from “hemp.” TTB is in the process of updating its [guidance](#) on the use of ingredients from hemp to reflect the recent changes to the law.

It remains TTB’s policy that it will not approve any formulas for alcohol beverages that contain ingredients that are controlled substances under the CSA. Even if an ingredient derived from cannabis is not a controlled substance because it meets the new definition of “hemp,” TTB continues to consult with the U.S. Food and Drug Administration (FDA), to determine if the use of hemp ingredients would violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). As described below, FDA has issued public statements explaining why some “hemp” ingredients are not permitted in food under the FD&C Act, which FDA administers.

After consultation with FDA, as set forth in more detail below, TTB has determined that, at this time, it will return for correction any applications for formulas containing “hemp” ingredients (other than ingredients derived from hemp seeds or hemp seed oil). Applicants will have the option of resubmitting the formula to TTB upon receipt of a favorable individual determination from FDA on the regulatory status of their ingredients. TTB will continue to process applications for formulas for alcohol beverages that contain ingredients derived from hemp seeds or hemp seed oil.

Recent Amendment to Law

The 2018 Farm Bill amended the definition of marijuana under the Controlled Substances Act (CSA), 21 U.S.C. § 802(16), to exempt “hemp,” which is defined in section 10113 as follows:

“The term ‘hemp’ means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”

The law explicitly preserved FDA’s authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act.

Existing TTB Guidance on Hemp Ingredients

Prior to the enactment of the 2018 Farm Bill, TTB issued [guidance](#) on the use of “hemp” ingredients in alcohol beverages. TTB is in the process of updating this guidance to reflect the recent changes to the law. In the interim, we note that alcohol beverages containing “hemp” ingredients (including alcohol beverages sold exclusively in intrastate commerce) continue to require formula approval under TTB regulations. TTB will continue to process applications for formulas for alcohol beverages that contain ingredients derived from hemp seeds or hemp seed oil.

TTB will continue to require formula applicants to submit laboratory analyses of “hemp” ingredients to ensure that the ingredients are not controlled substances under Federal law. TTB will not approve any formulas or labels for alcohol beverage products that contain a controlled substance under Federal law, including marijuana. In determining whether an ingredient is a controlled substance, TTB will continue to consult with the Drug Enforcement Administration where appropriate.

Consultation with FDA

As TTB noted in its guidance, TTB also consults with FDA on ingredient safety issues where appropriate. In some cases, TTB may require formula applicants to obtain documentation from FDA indicating that the proposed use of an ingredient in an alcohol beverage would not violate the FD&C Act.

After enactment of the 2018 Farm Bill, FDA Commissioner Scott Gottlieb, M.D., issued a [statement](#) noting that it remains unlawful under section 301(II) of the FD&C Act to introduce or deliver for introduction into interstate commerce any food to which CBD or THC has been added. On April 2, 2019, Dr. Gottlieb [announced](#) that FDA will hold a [public hearing](#) on May 31, 2019, in part to obtain scientific data and information about the safety of products containing cannabis or cannabis-derived compounds.

FDA also updated its website to include [FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers](#). Among other things, the updated Questions and Answers note that ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of section 301(II) of the FD&C Act, and therefore might be able to be added to food. However, FDA stressed that food companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the requirements for food additive approval and substantiation of evidence for Generally Recognized as Safe (GRAS) status.

FDA has advised us that, in evaluating the safety of any food ingredient, the agency applies the rigorous, science-based food safety standards in the FD&C Act and implementing regulations. Information about the [recommended toxicological testing](#) for ingredients used in food and [contact information for general questions](#) can be found on the FDA website. Applicants seeking to obtain an individual response on the regulatory status of their ingredient (e.g., via a GRAS notice) should contact FDA’s Office of Food Additive Safety directly at (240) 402-1200 before conducting studies or preparing documentation.

Questions. If you have any questions concerning this circular, please contact the Regulations and Rulings Division at (202) 453-2265 or use the [contact us form](#).

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