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FDA Issues Draft Guidance for Developers of Drugs Containing Cannabis and Opens Comment Period

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The 2018 Farm Bill greatly expanded the potential to conduct clinical research on at least some cannabis compounds by removing hemp from the list of controlled substances, but left unanswered a number of questions regarding the use of hemp compounds for drug development. In an effort to further clarify the 2018 Farm Bill's effect on clinical research into the development of drugs containing cannabis and cannabis-derived compounds, the U.S. Food and Drug Administration ("FDA") recently issued a draft guidance document titled "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research." The document responds to issues and questions raised during the FDA's May 2019 public hearing on the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived products, and provides specific guidance on (1) where drug developers may source cannabis and cannabis-derived compounds for clinical research, (2) general quality considerations, and (3) calculating the THC content in raw materials, extracts, and finished products.

Prior to enactment of the 2018 Farm Bill, there was a single federally legal source of cannabis for clinical research, that which was grown at the University of Mississippi under contract with the National Institute of Drug Abuse's Drug Supply Program. Obtaining cannabis under the Drug Supply Program was notoriously difficult and involved interactions with multiple federal agencies, including the FDA, the National Institute of Drug Abuse, and the Drug and Enforcement Administration. In light of the 2018 Farm Bill's removal of hemp from the list of controlled substances,[1] the FDA confirms in its draft guidance that hemp may serve as a source of cannabis and cannabis-derived compounds for drug development and that such hemp does not need to be sourced from the federal Drug Supply Program. Clinical researchers should, however, ensure that any hemp sourced for clinical trials was grown by a properly licensed hemp producer.[2]

With regard to quality considerations, drug developers are generally required to demonstrate to the FDA their ability to ensure the quality, purity, and potency of their investigational drug. In the context of investigational drugs containing cannabis or cannabis-derived compounds, the FDA's draft guidance sets forth a number of recommendations to meet the agency's expectations, including characterization of the cannabis via a chemical fingerprint to ensure batch-to-batch consistency, and testing for residual pesticides.

Finally, the FDA's draft guidance suggests that drug developers and clinical researchers should calculate the level of THC in their investigational drug products early in the development process to determine whether or not the threshold of 0.3 percent delta-9 THC by dry weight is exceeded. Whereas calculating the amount of a substance in a botanical raw material by dry weight is a relatively standard procedure, the FDA acknowledges that this method has limited utility for intermediates such as solutions, extracts in solutions, and finished products. For such products, the draft guidance recommends basing the calculation of delta-9 THC percentage on the composition of the formulation with the amount of water removed, including any water that may be contained in excipients.

The FDA has opened a 60-day comment period and has specifically requested feedback on its recommendation for calculating THC content and the appropriate manufacturing controls over materials that cross under the 0.3 percent threshold during the production process. The agency will accept comments on the draft guidance until September 21, 2020.

A copy of the draft guidance document can be found here: https://www.fda.gov/media/140319/download

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If you have any questions concerning these developing issues, please do not hesitate to contact either of the following Paul Hastings Washington, D.C. lawyers:

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[1] Hemp is defined to include cannabis and derivatives or extracts of cannabis with no more than 0.3 percent by dry weight of the compound delta-9 THC on a dry-weight basis.

[2] To qualify as hemp, the material must have no more than 0.3 percent delta-9 THC on a dry-weight basis. A properly licensed producer would give assurances that the material to be supplied meets this limitation.