

President Trump's Consideration of Cannabis Rescheduling: Creates Big Compliance Risks

Companies should use approved cannabis suppliers to substantiate any claims or risk losing millions of dollars.

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/EINPresswire.com/ -- President Donald Trump's recent announcement that he is considering rescheduling cannabis from Schedule I to Schedule III has ignited excitement across the cannabis, pharmaceutical, and consumer packaged goods (CPG) industries. While the move could unlock significant sales and research opportunities, experts warn it will also create costly misunderstandings among companies eager to make health claims.

For years, public companies, especially in the Pharmaceutical and CPG sector have largely avoided the cannabis market due to its Schedule I status and the legal uncertainties that come with it. However, numerous top executives at well-known public companies have privately expressed their intent to begin research and eventually enter the cannabis market once rescheduling occurs. These executives see significant opportunities for the treatment of conditions such as pain, sleeplessness and anxiety through the introduction of new products or brand extensions. The President's announcement is creating immediate demand for DEA-sourced cannabis for research. "We're fielding requests from public companies planning to enter the market upon rescheduling," stated Richard Shain, founder of Maridose LLC, "Companies should be securing relationships with a DEA licensed supplier now to avoid future supply problems."

"Many businesses will see rescheduling as a green light to market cannabis-based health products," continued Shain, "But even as a Schedule III drug, cannabis remains a controlled substance under federal law. If you want to make health claims, the research behind those claims must be conducted using cannabis sourced from a DEA-licensed manufacturer or distributor. Anything else risks wasting millions of dollars and having your data rejected."

Federal law is clear. Under 21 U.S.C. § 823, researchers working with controlled substances, whether Schedule I, II, or III must obtain their research material from a DEA-registered manufacturer (such as Maridose) or through a registered distributor who in turn must source



from a registered manufacturer. The FDA will not accept clinical trial data for a controlled substance if the material used came from an unlicensed source.

The upside for the eight licensed DEA Manufacturers is substantial. When rescheduling occurs, the number of researchers approved to work with Schedule III drugs is expected to increase by about eight-fold. That's a massive expansion in legitimate research capacity and DEA-licensed suppliers are uniquely positioned to meet that demand. A list of the 8 approved DEA Manufacturers is available at <https://www.nccih.nih.gov/grants/dea-approved-bulk-cannabis-suppliers>

Companies attempting to shortcut these rules by using cannabis from non-DEA sources in clinical trials or making unsubstantiated claims risk FDA enforcement actions, regulatory delays, and reputational harm.

"Rescheduling will open doors for ground breaking research and product innovation," Shain concluded. "But those doors still lead through the same regulatory hallways. Only those who follow the path laid out by the FDA and DEA will be able to walk through them."

About Maridose LLC

Maridose is a DEA-licensed Bulk Manufacturer of cannabis. The company supplies cannabis flower and extracts to researchers for biopharmaceutical research and product development. The company was selected by the U.S. DOJ and DEA to legally cultivate and sell cannabis. Maridose's Center of Excellence is located at TechPlace in Brunswick Landing, Maine providing best-in-class cannabis cultivation, research and product development.

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