

Office of Information and Regulatory Affairs Office of Management and Budget

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Cannabidiol Enforcement Policy; Draft Guidance for Industry;
Availability

Executive Order 12866 Meeting
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Quick stats on U.S. hemp production program

- 2018 Farm Bill hemp provisions enacted by Trump administration
- 48 states have approved hemp production programs
- 290k+ acres in 2019 (cultivated, 466k+ acres licensed in 2020)
 - 25.5k acres in 2017 (cultivated)
- 19,689+ licensed producers in 2019
 - 1,456 licensed producers in 2017
- 85%+ of crops grown for botanical extraction of cannabinoids and terpenes including cannabidiol (CBD)
- Hemp farmers are optimistic, resilient, and excited about this new crop (see attached letter to President Trump)

Quick stats on U.S. consumers and CBD

- 90% of U.S. consumers are familiar with CBD. (according to New Frontier Data survey, 2020)
- 26% of U.S. consumers have used CBD products. (Consumer Reports survey, 2019)
- Almost three-quarters of people who took CBD said it was at least moderately effective for the main reason they took it, with 48 percent of them saying it was very or extremely effective. (Consumer Reports survey, 2019)
- The majority of U.S. consumers (92%) incorrectly assume or have no idea if federal consumer protections and safety oversight are in place when they are not.
- U.S. consumer demand is great for hemp CBD products and U.S. hemp farmers are well positioned to meet the demand.

Issue at hand

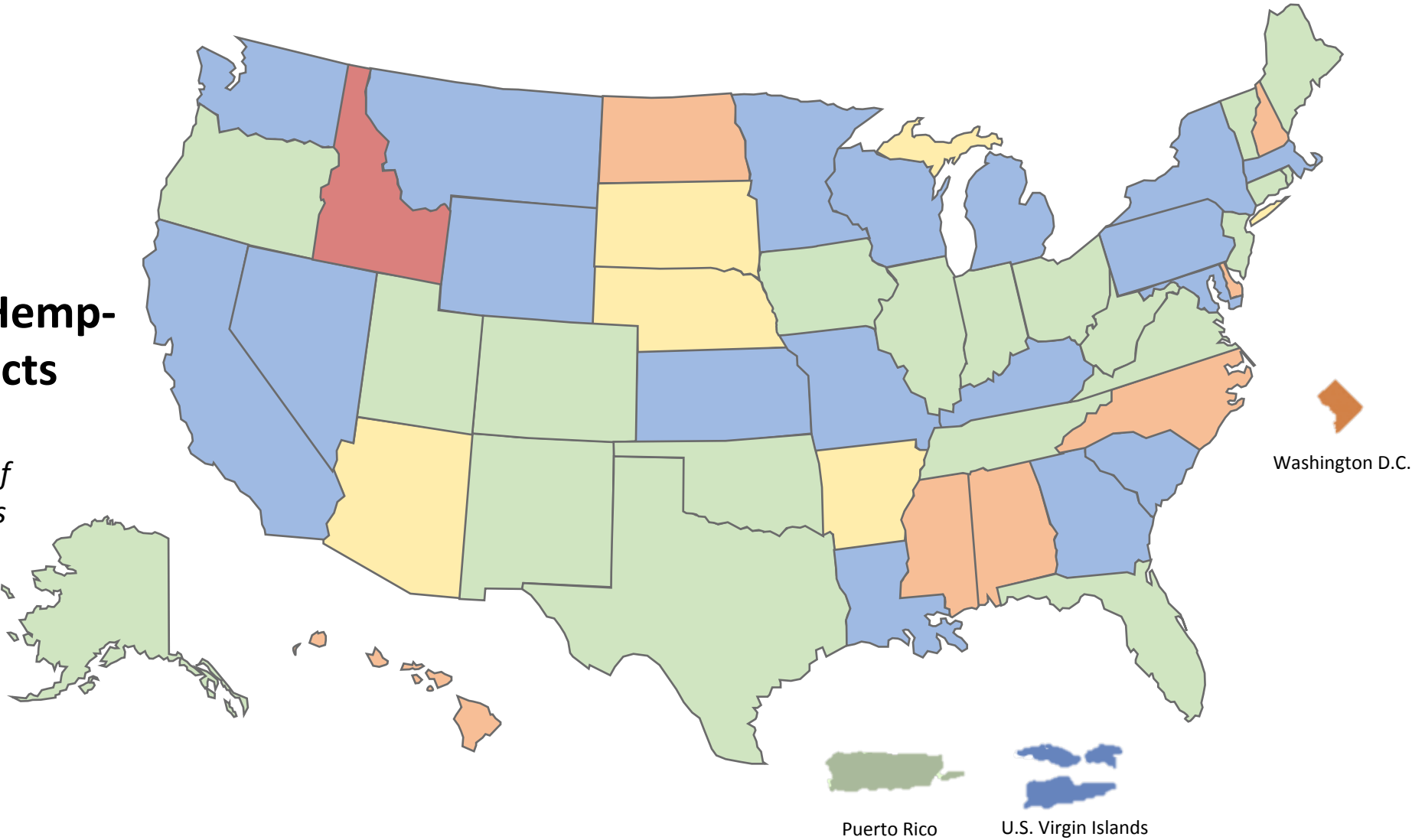
- Hemp-derived cannabidiol (CBD) is a sought after ingredient for food and dietary supplement products by consumers and innovators.
- CBD-containing products have been in the market for years. New products continue to enter the marketplace and are widely available.
- The 2018 U.S. Farm Bill opened a new crop for U.S. farmers and a domestic source for CBD.
- However, FDA's non-final position that all cannabidiol is prohibited from use in food and dietary supplement products has created market chaos and does not accurately reflect the law.
 - FDA relies on the drug exclusion provisions and points to a study on a cannabidiol isolate for a disease condition as the basis.
 - However, there is not broad consensus that the 'article' (cannabidiol isolate) used in the drug is the same as all hemp-derived CBD used in food and supplement products.

The result of FDA's action

- There is tremendous consumer demand for high quality, safe CBD-containing products, yet, consumers are left vulnerable.
 - FDA has stood down on enforcing the Food, Drug, and Cosmetic Act (FDCA), which is designed to ensure products are safe, GMP compliant, and that non-compliant companies are held accountable.
- Individual states forced to enact a patchwork of hemp-CBD policies.
 - As a means to support the domestic hemp program, states implemented programs to allow hemp-derived cannabidiol products in the market.
 - As more states enact programs, the long-term concern is the clash between federal and state regulations and even more consumer confusion.
- Valuable multi-billion dollar end markets for hemp farmers and processors have been compromised by an overly broad interpretation of the drug exclusion provisions.
 - The nascent domestic hemp production program has been undermined by FDA's non-final agency position, of which is counter to the intent of the 2018 Farm Bill.

The United States of Hemp-Derived CBD Products

State and territory
categorization for the Sale of
Hemp-Derived CBD Products



Prohibited Under State Criminal Laws: 2



Limited Protections For Program Registrants: 7



No Policies or Statements on Product Type: 4



Prohibitive Policies or Product-Type Restrictions: 19



No Specific Product-Type Restrictions: 21

Key concerns for CBD products in marketplace

- Label accuracy: what is on the label should be in the product
- Health Claims: product claims (if any) must be compliant and non-disease
- Supply chain integrity: full traceability with validated test protocols
- Manufacturing practices: cGMPs, SOPs, test methods

Fortunately, the U.S. Food, Drug, and Cosmetic Act already addresses each of these concerns.

- Dietary Supplement Health and Education Act, 21 CFR 111
- Food Safety Modernization Act, 21 CFR 117
- Facility registration, labeling requirements, adverse event reporting

Therefore,

- Special regulations and guidance documents for CBD are not needed. Existing regulations should be applied to hemp just as any other ingredient, herb or botanical.
- The FDCA is comprehensive and provides pathways to market for CBD. Remove the drug exclusion barrier and let the FDCA work.
- Farmers are ready to contribute to our nation's economic recovery. Let them.

Our ask,

- FDA stay or withdraw their non-final agency position and stand-up the FDCA.
- FDA has publicly stated a regulatory path is forthcoming and now is the time. Further delays are a burden on American farmers and leaves consumers vulnerable.
- Support American consumers by enforcing the FDCA to ensure hemp products meet existing requirements including GMP, accurate labeling, and testing.
- Support U.S. hemp farmers by opening end markets and applying the law fairly to hemp just as any other food or dietary supplement ingredient.



Thank you.

Please reach out with further questions.

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