U.S. Hemp Roundtable

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STATEMENT BY U.S. HEMP ROUNDTABLE CONCERNING FDA ANNOUNCEMENT ON HEMP-DERIVED CBD

WASHINGTON D.C. — Today, the U.S. Food and Drug Administration (FDA) announced plans to establish a new regulatory pathway for hemp-derived cannabidiol (CBD), stating that existing foods and dietary supplement authorities provide only limited tools for managing many of the risks associated with CBD products. The agency claims a new regulatory pathway would benefit consumers by providing safeguards and oversight to manage and minimize risks related to CBD products. The FDA also denied three citizen petitions from the Consumer Health Products Association (CHPA), the Council For Responsible Nutrition (CRN), and the Natural Products Association (NPA) requesting rulemaking to allow the marketing of CBD products as dietary supplements.

Jonathan Miller, General Counsel of the U.S. Hemp Roundtable, issued the following statement —

"We were extremely disappointed today with the FDA's announcement concerning the regulation of CBD.

When it comes to the safety of CBD, the FDA gets it wrong. Contrary to the FDA's continued assertions regarding the safety of CBD, there is clear, established evidence of safety over the years. CBD products have been sold at retail for nearly a decade with no significant safety issues. The Roundtable recently met with the FDA and shared a broad range of safety studies showing that standard CBD serving sizes are safe, while the FDA continues to rely on pharmaceutical studies that show risk at significantly larger doses that are not commonly found in CBD products sold at retail.

We therefore see no need for FDA to go through the lengthy, burdensome exercise of establishing a new regulatory pathway for CBD, or other hemp-derived cannabinoids. This action would be unprecedented and is unnecessary given the existing dietary supplement and food pathways provided under the Federal Food, Drug, & Cosmetic Act, which include robust, comprehensive requirements aimed at ensuring the safety and quality of products, in addition to extensive FDA regulations covering the manufacturing, labeling, and marketing of products. We strongly disagree that these are "limited tools," with requirements that include the following:

- compliance with mandatory current Good Manufacturing Practices (cGMPS) to help prevent contamination and adulteration, as well as detailed requirements for ensuring sanitary practices, proper training of personnel, cleaning of equipment,
- and in-process controls aimed at product quality and safety;
- mandatory facility registration and compliance the Food Safety and Modernization Act, which provides FDA with mandatory recall authority and other enforcement tools aimed at ensuring compliance with food safety standards;
- assuring there is adequate safety to support the intended use of ingredients through NDI notifications or GRAS procedures, which require adherence to specific safety standards outlined in FDA regulation, law, and guidance;
- detailed requirements for nutrient content claims, health claims, and structure/function claims;
- appropriate labeling to ensure safe use of the product, as well as prohibitions on false or misleading labeling, with additional and stringent substantiation requirements covering a wide range of claims imposed by FTC;
- and for dietary supplements, adverse event reporting and recordkeeping requirements, which are enforced through GMP inspections.

With all of these tools in place as part of the existing, well-established pathways, the FDA's decision is unwise. To the extent FDA believes its current resources are not sufficient to implement and enforce existing requirements, the Roundtable supports additional appropriations to assist FDA in its compliance efforts.

However, there is one area in which we are in strong agreement with the FDA: As we have advocated for years, a legislative solution is necessary to allow the marketing of hemp-derived cannabinoids including CBD as dietary supplements and foods. We look forward to working with the large, bi-partisan coalition that has developed in Congress to re-introduce legislation in this new Congress in the coming days to direct FDA to utilize the existing regulatory pathways for CBD and other hemp-derived cannabinoids, one that ensures the safety and quality of products. We also remain willing to work with the FDA to ensure that hemp-derived cannabinoids like CBD are safe and adequately regulated."

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ABOUT

The U.S. Hemp Roundtable is the hemp industry's national advocacy organization, a coalition of dozens of leading companies and organizations committed to safe hemp and CBD products. The Roundtable proudly works in partnership with the industry's leading national, regional and state grassroots organizations, and is leading the way forward for hemp and CBD products through education and action. More at hempsupporter.com.