Science Board to the Food and Drug Administration via Videoconference June 14, 2022

BACKGROUND MATERIALS

1. Is It Really 'FDA Approved'?

https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved A guide to how the FDA regulates products for people — and what the agency does (and doesn't) approve.

- 2. Safety of CBD in Humans A Literature Review <u>https://www.fda.gov/media/152317/download</u> FDA literature review on the safety of CBD in humans, including publicly available information contained in the FDA clinical review of the Epidiolex New Drug Application (NDA) and Epidiolex labeling; published, peer-reviewed scientific literature on PubMed; and CBD clinical trials that were not yet published but had posted safety results on ClinicalTrials.gov (i.e., not including trials that posted only efficacy results but not safety results).
- Use and Perceptions of Cannabidiol Products in Canada and in the United States <u>https://doi.org/10.1089/can.2020.0093</u> A study characterizing use and perceptions of cannabidiol (CBD) products.
- 4. The Safety and Regulation of Natural Products Used as Foods and Food Ingredients <u>https://doi.org/10.1093/toxsci/kfr198</u> A review of the safety assessment and regulation of botanical dietary supplements by the FDA. Please focus on the second section "Natural Products Used as Dietary Supplements."
- FDA'S food ingredient approval process: Safety assurance based on scientific assessment <u>https://doi.org/10.1016/j.yrtph.2008.10.003</u> A review of the basic components of the FDA's decision-making process for evaluating the safety of new food additives.