# FDA Public Hearing:
# Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

May 31, 2019

# FDA considers cannabidiol (CBD) in foods/supplements to be prohibited under §321(ff)(3)(B)

- IND preclusion language was added to DSHEA to protect the commercial interests necessary to incentivize drug development.
- Permitting CBD use in dietary supplements and food is first a commercial issue, not a safety issue.

***An "article" that (1) was "authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public"; and (2) "which was not before such an approval . . . marketed as a dietary supplement [or food]."***

# FDA has authority to override the general prohibition

- Congress gave FDA the discretion to issue regulations allowing an article to be used in a dietary supplement or food.
- The final clause recognizes circumstances would arise that would justify exceptions to the general presumption.
- When should FDA permit a drug firm to gain a monopoly over the "article," and how sweeping should that monopoly be?

***"…unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful…"***

# FDA has authority to override the general prohibition

- The §321(ff)(3)(B) decision is not a question of safety.
- Framework already exists to ensure the safety of a dietary supplement or food through other statutory provisions and regulations.
  - e.g., NDI notifications, GRAS certifications and food additive petitions.
  - These take into account safety under the proposed conditions of use.

***"…unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful…"***

# FDA must address the safety of CBD—but on a product-specific basis

- Addressing these issues sequentially, is not an abdication of safety concerns.
- It permits FDA to address safety in the context of each regulatory channel, unique delivery form, ingredient matrix (isolate v. full spectrum), and dosage; it should be product specific.
- Safety is always Job One–but it does not have to be the first job; resolve the §321(ff)(3)(B) issue first.

# FDA must act quickly to address a market out of control

- Compliance with the existing regulatory framework for these products is critical for consumer safety and marketplace trust.
- FDA must enforce existing category-wide regulations irrespective of the specific fate of a its decision on the legality of CBD in foods and supplements.
  - Facility registration, cGMPs, labeling, mandatory adverse event reporting, etc...
- Once a new framework is in place, FDA should treat all CBD-containing dietary ingredients as New Dietary Ingredients, subject to the NDIN, GRAS, or Food Additive requirements.

# CBD safety: Authoritative reviews

- "…well tolerated with a good safety profile…"


- "…well tolerated at doses greater than 1000 mg per day…"


- "In general, the risks associated with CBD treatment appear acceptable…"

# CBD safety: Systematic reviews

*Current Drug Safety*, 2011, *6*, 000-000

**Safety and Side Effects of Cannabidiol, a *Cannabis sativa* Constituent**

Mateus Machado Bergamaschi[1,2], Regina Helena Costa Queiroz[1], José Alexandre S. Crippa[*,2] and Antonio Waldo Zuardi[2]

- "…CBD is well tolerated and safe in humans at high doses and with chronic use."

- "…the often described favorable safety profile of CBD in humans was confirmed and extended by the reviewed research."

Cannabis and Cannabinoid Research
Volume 2.1, 2017
DOI: 10.1089/can.2016.0034

Cannabis and Cannabinoid Research

Mary Ann Liebert, Inc. publishers

REVIEW Open Access

**An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies**

Kerstin Iffland and Franjo Grotenhermen

# CBD safety references


- WHO, 2018. CBD, Critical Review Report. Available at: https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf
- FSANZ, 2016. CBD Hazard Profile. Available at: http://www.foodstandards.gov.au/code/proposals/Documents/P1042%20Low%20THC%20hemp%20CFS%20SD2%20Cannabidiol%20hazard.pdf
- U.S. FDA, 2018. Drug Approval Package: Epidiolex (Cannabidiol). Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365orig1s000toc.cfm
  - Summary, Safety review starts on page 38, FDA's own conclusions on safety on page 51: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000SumR.pdf
- Bergamaschi et al., *Current Drug Safety*, 2011, Vol. 6, No. 4
- Iffland and Grotenhermen, *Cannabis and Cannabinoid Research* 2017, 2.120

# Thank You