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Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
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April 17, 2023

Dr. Robert M. Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Califf,

The Committee on Oversight and Accountability is investigating the Food and Drug Administration's (FDA) recent announcement regarding its authority to regulate CBD products as dietary supplements.[1] The announcement states that the FDA does not believe its current regulatory framework allows for regulation of cannabidiols (CBD). The mission of the FDA is to advance[e] the public health by helping to "speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health."[2] We seek documents and information to enable oversight of the FDA's actions related to this announcement.

CBD is an increasingly popular product among adults and has seen an uptick in usage in recent years. According to a recent World Health Organization (WHO) report, "across a number of controlled and open label trials of the potential therapeutic effects of CBD it is generally well tolerated, with a good safety profile."[3] As science is catching up regarding the safety of CBD usage, it is imperative that the FDA recognize its role in regulating these products. The lack of regulation of non-intoxicating CBD products have allowed for potentially dangerous products to enter the market in the form of Delta-8 and other hemp-derived intoxicants, leading to increasing concern that some products contain potentially dangerous ingredients due to the lack of regulation.[4] Proper regulation from the FDA would not only prevent bad faith actors from entering the market but will increase the amount of good faith manufacturers' contributions of a useful product for the American public.

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[1] Statement from Janet Woodcock, M.D., FDA, FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward (January 25, 2023).
[2] What We Do, FDA (March 28, 2018) (https://www.fda.gov/about-fda/what-we-do#:~:text=FDA%20Basics-,FDA%20Mission,and%20products%20that%20emit%20radiation).
[3] World Health Organization, Cannabidiol Pre-Review Report 13 (November 6-10, 2017), https://hempsupporter.com/assets/uploads/WHO-CBD-report.pdf.
[4] *Unregulated Hemp-Derived CBD and THC Products are Often Mislabeled and May Contain Toxic Chemicals*, DREXEL UNIVERSITY (August 4, 2022).

FDA's claim of a lack of a regulatory pathway is not only an insufficient rationale for inaction, but it is directly affecting the welfare of the American public. Without allowing for therapeutic CBD products to be regulated as dietary supplements such as melatonin or fish oils, the good faith actors in the industry are unable to enter the market and provide people with helpful products because they are currently not distinguished under the FDA from the intoxicating products containing Delta-8. It is imperative that the FDA engages in this regulation quickly, safely, and efficiently to provide proper guidance to the American people about the safety of CBD products.

To assist the Committee in conducting oversight of the FDA's actions related to the CBD announcement, please provide the following documents and information no later than May 1, 2023:

1. All documents, communications, and drafts related to the January 26 announcement titled "FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward";

2. All documents and communications relating to the FDA's assessment of the existing regulatory framework at issue regarding CBD;

3. All scientific data, reports, and research in the possession of the FDA relating to the safety of CBD products for consumption.

Attached are instructions for producing the documents and information to the Committee. If you have any questions, contact the Committee on Oversight and Accountability Majority staff at 202-225-5074.

The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate, "any matter" at "any time" under House Rule X. Thank you for your attention to this important matter.

Sincerely,

James Comer
Chairman
Committee on Oversight and Accountability

cc: The Honorable Jamie Raskin, Ranking Member
Committee on Oversight and Accountability