November 17, 2020

Steve Mister
President & CEO
and
Megan Olsen
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Council for Responsible Nutrition
1828 L Street, N.W., Suite 810
Washington, DC 20036

Sent via email to: molsen@crnusa.org

Re: Docket No. FDA-2020-P-1582

Dear Petitioner:

This is an interim response to the Citizen Petition (FDA-2020-P-1582) ("Petition") you filed with the Food and Drug Administration (FDA or Agency) on June 16, 2020.

Your petition requests that FDA 1) Exercise FDA's statutory authority and discretion under 21 U.S.C. § 321(ff)(3)(B) (Section 201(ff)(3)(B) of the FDCA) to issue a regulation finding that hemp-derived CBD is a lawful dietary ingredient; 2) Provide guidance clarifying when a substance is considered "an article" as that term is used in 21 U.S.C. § 321(ff)(3)(B); and 3) Enforce existing dietary supplement regulations already promulgated in the FDCA and Title 21 of the Code of Federal Regulations (CFR) with respect to hemp-derived CBD products being marketed as dietary supplements.

The Agency will require additional time to issue its final response because of the complexity of issues raised in your petition. FDA will issue a final response to your citizen petition after completing the analyses of all of the legal and policy issues related to this petition.

Sincerely,

Amy Abernethy
Principal Deputy Commissioner for FDA