June 16, 2020

David Spangler
Senior Vice President
and
Anne Marie Murphy
Deputy General Counsel
Consumer Healthcare Products Association
1625 Eye Street N.W., Suite 600
Washington, DC 20006

Sent via email to: ammurphy@chpa.org

Re: Docket No. FDA-2019-P-5394

Dear Petitioner:

This is an interim response to the Citizen Petition (FDA-2019-P-5394) ("Petition") you filed with the Food and Drug Administration (FDA or Agency) on November 14, 2019.

Your petition requests that FDA 1) establish a regulatory pathway to legally market dietary supplements containing cannabidiol (CBD) derived from hemp by promulgating regulations under 21 U.S.C. § 321(ff)(3)(B), stating that the article, hemp-derived CBD, is lawful under the Federal Food, Drug, and Cosmetic Act (FD&C Act); 2) maintain the status quo for medicines containing CBD, meaning continue to enforce the statutory requirements and protections under the new drug application process, including with regard to approved indications and established safe dosages; 3) continue and increase enforcement action against unscrupulous manufacturers making illegal drug claims or otherwise failing to comply with the FD&C Act with regard to CBD-containing products; and 4) continue to monitor emerging safety issues, if any, concerning CBD-containing products.

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,

Lowell Schiller
Principal Associate Commissioner for Policy

U.S. Food and Drug Administration
Office of Policy
Silver Spring, MD 20993
www.fda.gov