DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 14, 2019

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA:

1. Establish a regulatory pathway to legally market dietary supplements containing 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 FDCA. FDA has the authority to act quickly under section 553(b) of the Administrative Procedure Act (AP A) to establish this pathway by issuing an interim final rule.

2. Maintain the status quo for medicines containing CBD, meaning continue to enforce the statutory requirements and protections under the NDA 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 FDCA with regard to CBD-containing products.

4. Continue to monitor emerging safety issues, if any, concerning CBD-containing products

Your submission was received by this office on 11/14/2019, and it was assigned docket number FDA-2019-P-5394. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard -S
Digitally signed by Karen Kennard -S
Date: 2019.11.14 17:08:29 -05'00'

Karen Kennard
Director
Dockets Management Staff
FDA/Office of Operations (OO)