FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

August 19, 2022

Daniel Fabricant, Ph.D.
Natural Products Association
440 1st Street, NW
Washington, DC 20001

Re: Docket No. FDA-2022-P-0600

Dear Dr. Fabricant:

This letter is a tentative response to your citizen petition dated February 21, 2022, requesting that the Food and Drug Administration (FDA or we) either:

1. Determine "that [cannabidiol] CBD is not excluded from the definition of a dietary supplement under 21 U.S.C. 321(ff)(3)(B)"; or
2. Exercise "enforcement discretion in a specific and selective manner over CBD products following a safety review of a notification on an individual dietary supplement product submitted consistent with 21 C.F.R. Part [sic] 190.6."

See Citizen Petition from Daniel Fabricant, Ph.D., Natural Products Association, to Dockets Management Branch, Food and Drug Administration, dated February 21, 2022 ("Petition") at page 2. Alternatively, your Petition asks that we recommend and support to the Secretary of the Department of Health and Human Services that FDA issue a regulation, after notice and comment, establishing that CBD is lawful under the Federal Food, Drug, and Cosmetic Act. See *id*.

We are advising you, in accordance with 21 CFR 10.30(e)(2)(iv), that we have not reached a decision on your Petition within the first 180 days because of the complex nature of your requests. However, be advised that we are actively evaluating your Petition and intend to respond when our review is complete.

Sincerely,

Cara Welch -S

Digitally signed by Cara Welch -S
Date: 2022.08.19 00:01:14 -04'00'

Cara Welch, Ph.D.
Director
Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition

CC: Dockets Management Branch, HFA-305

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
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