U.S. FOOD & DRUG ADMINISTRATION

Jianyi Zhang MD, PhD, MS
(b) (6)

June 23, 2023

Re: Docket No. FDA-2022-P-2516

Dear Dr. Zhang:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 21, 2023, which amended the citizen petition that you submitted on October 12, 2022. Your amended petition requests that the FDA: (1) approve combined "Potential Therapeutic Drugs (PTDs)" intended to treat patients with Alzheimer's disease and those patients with medical conditions currently without any effective medication with only a demonstration of safety and without any pre-market studies; and (2) amend relevant regulations to allow combined PTDs "to treat patients with medical conditions currently without any effective medication" with only a demonstration of safety.

FDA has been unable to reach a decision on your amended petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)).[1] We will respond to your amended petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S
Digitally signed by Carol Bennett -S
Date: 2023.06.23 10:26:43 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

[1] We note that you submitted an amended citizen petition before the 180 day period from submission of your initial petition had passed. We also note that the 180-day period from submission of your amended petition has not yet passed. We anticipate that FDA will not be able to reach a decision on your amended petition within 180 days of the February 21, 2023, submission, given the complex issues that it presents.

U.S. Food & Drug Administration
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