



Jay R. Deshmukh
Kasowitz Benson Torres LLP
1633 Broadway
New York, NY 10019

July 15, 2024

Re: Docket Nos. FDA-2024-P-0521 and -0522

Dear Petitioner:

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 January 25, 2024, and submitted on behalf of Adventapharma DWC LLC. Your petitions request that the Agency investigate specific dosing amounts for the applicable generic drugs.

FDA has been unable to reach a decision on your 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)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett
-S

Digitally signed by Carol
Bennett -S
Date: 2024.07.15 13:53:40
-04'00'

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