U.S. FOOD & DRUG ADMINISTRATION

April 18, 2023

Meg D. Newman, MD, FACP
UCSF Senate Emeritus-Medicine
1484 16th Avenue
San Francisco, CA 94122-3510

*Sent via email to:* meg.newman@ucsf.edu

Re: Docket No. FDA-2020-P-2353

Dear Dr. Newman:

I am writing to inform you that the Food and Drug Administration (FDA, we) has not yet reached resolution of the issues raised in your citizen petition, received by the Dockets Management Staff on October 21, 2022. In your petition, you request that FDA take certain actions with respect to products for the treatment of *Clostridium difficile* (*C. difficile*) infection. Specifically, you request FDA to take two actions:

1. "[C]onsider the data already collected for live microbiome-based treatments for the prevention of recurrent [*C. difficile*] to be sufficient for considering these products for approval."
2. "[R]efrain from requiring additional placebo-controlled trials of live microbiome-based treatments for the prevention of recurrent [*C. difficile*]."

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA's 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,

Peter Marks

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff