October 21, 2022

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA consider the data already collected for live microbiome-based treatments for the prevention of recurrent CDI to be sufficient for considering these products for approval and refrain from requiring additional placebo-controlled trials of live microbiome-based treatments for the prevention of recurrent CDI was received by this office on and processed under CFR 10.30 by this office on 10/21/2022.

It was assigned docket number FDA-2020-P-2353. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.10.28 12:28:58 -04'00'

Dynna Bigby
Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)