December 29, 2020

Paul Kim
Counsel for Microbiome Therapeutics Innovation Group
Foley Hoag, LLP
1717 K Street, N.W.
Washington, DC 20006

Re: Docket No. FDA-2020-P-1633

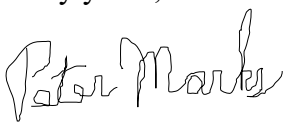
Dear Mr. Kim:

I am writing to inform you that the Food and Drug Administration (FDA, the Agency, or we) has not yet reached resolution of the issues raised in your citizen petition (Petition) on behalf of petitioner, the Microbiome Therapeutics Innovation Group (MTIF), and received by the Dockets Management Staff on July 2, 2020. In your Petition, you request that FDA take certain actions with respect to fecal microbiota transplantation (FMT). Specifically, you request FDA to take four actions:

1. Finalize the 2016 draft guidance and specify that the sponsors and manufacturers of commercial-scale FMT products are required to operate under an IND and must therefore implement and follow the same rigorous clinical, regulatory manufacturing and quality controls applicable to other microbiota drug products that are being developed for licensure under FDA oversight. Holding stool banks and contract manufacturers to IND regulations will assure compliance with the screening and other safety-based precautions outlined in recent FDA safety alerts, which are currently voluntary in nature.
2. Retain the safe harbor for the use of FMT when the stool donor and stool are qualified by screening and testing performed under the direction of the licensed health care provider for the purpose of providing the FMT product to treat his or her own patient.
3. Provide additional guidance with respect to the comprehensive approach FDA is considering for the study and use of FMT products under an IND.
4. Reiterate that the FMT enforcement discretion policy is an interim policy, and is subject to change or revocation following further evaluation of the policy's effects on patient safety and efficacy. If a sponsor of a microbiota drug for C. diff. infection receives marketing approval, MTIG requests that FDA reconsider whether enforcement discretion remains the correct action to ensure safe and effective access to patients.

FDA takes these issues seriously but has not yet reached a resolution on your Petition because of the existence of other FDA priorities. 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 yours,



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

cc: Dockets Management Staff