**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration
Rockville, MD 20857

July 6, 2020

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*Sent via email to:* pkim@foleyhoag.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following four actions described below:

1) Finalize the 2016 draft guidance and specify that the sponsors and manufacturers of commercial-scale FMT products are required to operate under an IND and must therefore implement and follow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.

Your submission was received by this office on 07/02/2020 and it was assigned docket number FDA-2020-P-1633. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.07.06 13:12:07 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
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