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Correspondence to “Escape Velocity—the Launch of Microbiome Therapies”

Bernat Olle,

Vedanta Biosciences Inc., Cambridge, Massachusetts, USA.

Ryan Ranallo,

Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Rockville, Maryland, USA.

L. Clifford McDonald

Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia, USA.

TO THE EDITOR:

We congratulate Kelly et al. on an excellent review of advances in microbiome therapeutic development [1]. The article states that FDA has approved the first two live biotherapeutic products (LBPs) for prevention of recurrent *Clostridioides difficile* infection and outlines important considerations in the future development of LBPs. We would like to draw attention to an important update on FDA terminology for further discussion.

We note that FDA did not use the term LBP to refer to the two referenced approvals. FDA instead uses the term “Fecal Microbiota Products” on the agency’s website [2] and the generic naming convention “fecal microbiota” [3] and “fecal microbiota spores” [4] in the corresponding Approval Letters to refer to the drugs’ active ingredients. We also note that Fecal Microbiota Products (FMPs) have variable strain composition and thus do not conform to the description and characterization of a drug substance described in the FDA’s chemistry, manufacturing, and control guidance for industry involving early clinical trials with LBPs [5].

We acknowledge that our publication in *Journal of Infectious Diseases*’s 2021 Supplement on “The State of Microbiome Science at the Intersection of Infectious Diseases and Antimicrobial Resistance” similarly used the term LBP in a manner inconsistent with FDA’s current terminology to refer to the products now termed Fecal Microbiota Products [6]. With the benefit of hindsight of FDA’s recent communications, it appears the agency intends to use the term LBP for products of defined composition and that many publications in the microbiome field are using the term inconsistently. We hope that aligning the terminology in academic and industry publications with FDA will advance the field and help advance FDA’s mission.

bolle@vedantabio.com .

Potential conflicts of interest. B.O. is an employee of, and owns stock options of Vedanta Biosciences, Inc.

Disclaimer:

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID). This letter was written by the National Institutes of Health (NIH) and CDC employees in the course of their usual duties without additional funding support.

References

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- [2]. <https://www.fda.gov/vaccines-blood-biologics/fecal-microbiota-products>
- [3]. November 30, 2022 Approval Letter - REBYOTA ([fda.gov](https://www.fda.gov))
- [4]. April 26, 2023 Approval Letter - VOWST ([fda.gov](https://www.fda.gov))
- [5]. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/early-clinical-trials-live-biotherapeutic-products-chemistry-manufacturing-and-control-information>
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