



April 25, 2013

C. Richard Boland, MD, AGAF, Chair
American Gastroenterological Association
4930 Del Ray Avenue
Bethesda, MD 20814-2513

Dear Drs. Boland, Vender, Deas, and Bousvaros,

Thank you for your recent inquiry to Dr. Hamburg regarding the use of fecal microbiota for transplantation (FMT) in people with *Clostridium difficile* infection. Your inquiry has been referred to me for response.

The Center for Biologics Evaluation and Research (CBER) is the lead center within FDA regarding the therapeutic use of FMT, also referred to as fecal transplantation or fecal bacterial therapy. FDA recognizes the potential importance of FMT for use in addressing human diseases or conditions and is holding a workshop on this topic in May (please see additional information below). As we explain below, fecal microbiota that falls with the definition of a biological product and drug is regulated by FDA.

Fecal microbiota when used to prevent, treat, or cure a disease or condition would fall within the definition of biological product as defined in section 351(i) of the Public Health Service Act [42 U.S.C. 262(i)] and the definition of drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)]. Fecal microbiota would also fall within the definition of a drug under the FDCA if it is intended to affect the structure or any function of the body of man. FDA has not approved any FMT products for therapeutic uses. A product intended for such use(s) would be an Investigational New Drug for which an Investigational New Drug application (IND) must be submitted.

With regard to your specific questions:

Is an IND required for *C. diff* only for clinical research study purposes or for all treatment of *C. diff* when using FMT?

Because FMT is not approved for any therapeutic purposes, for any use of FMT in a clinical investigation or for treatment of *C. diff*, an IND would be needed. Please see the information in the above paragraph.

Is an IND required for all uses of FMT for all disease state applications other than *C. diff*?

As conveyed above, an IND is needed for the use of FMT to treat a disease.

What steps will the FDA take to make known its position on FMT for C. diff?

FDA is working to facilitate the clinical development of FMT. CBER and NIH's National Institute of Allergy and Infectious Diseases (NIAID) are holding a public workshop on May 2 and 3, 2013 in Bethesda, MD to provide a forum for the exchange of information, knowledge, and experience between CBER, NIAID, and the scientific-medical community regarding this emerging field. Information on this workshop can be found at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm341643.htm>

What guidance can the FDA offer to our societies as to the most effective way to inform our members on this matter?

We believe that your members may be interested to know that we are convening a public workshop on this topic. We view this public workshop as very important in helping to ascertain the status of the science and in helping to inform us as we further consider this matter. We hope that you will send a representative from each of your respective societies to the workshop.

Thank you for contacting us.

Sincerely,



Karen Midthun, M.D.
Director
Center for Biologics Evaluation and Research