FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
176th Meeting of the Vaccines and Related Biological Products Advisory Committee
September 22, 2022
DRAFT AGENDA

Topic: This committee will meet in open session to discuss the Biologics License Application # 125739 (BLA - 125739) from Rebiotix Inc. for a product, Rebyota (Fecal Microbiota, Live), with a requested indication to "reduce the recurrence of *Clostridioides difficile* infection (CDI) in adults following antibiotic treatment for recurrent *Clostridioides difficile* infection."

Time	Presentation/Presenter
8:30 a.m. ET	**Opening Remarks: Call to Order and Welcome (10 min)** Hana El Sahly, M.D. Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)** Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division of Scientific Advisors and Consultants, CBER, FDA
9:00 a.m. ET	**FDA Introduction (30 min including Q &A))** **Welcome (5 Min)** • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA **Biologics License Application for Rebyota (Fecal Microbiota, Live) (20 min)** • Qun Wang, Ph.D. Review Committee Chair Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR) CBER, FDA Q & A – 5 min
9:30 a.m. ET	**CDC Presentation (30 Min including Q &A)** **Current epidemiology of *Clostridioides difficile* infection (CDI) in adults in the United States (20 Min)** • Alice Y. Guh, M.D. MPH Medical Officer Division of Healthcare Quality Promotion Centers for Disease Control and Prevention (CDC)

	Q & A – 10 Min
10:00 a.m. ET	**Sponsor (Rebiotix inc,) Presentation (90 Min including Q&A)** **Rebyota (Fecal Microbiota, Live) for patients with recurrent *Clostridioides difficile* infection (60 min)** **Introduction** Lee Jones, Founder and Past President and CEO of Rebiotix Incorporated (Inc.), a Ferring Company **Effective Management of *C difficile*, An Unmet Clinical Need** Sahil Khanna, MBBS, MS, Professor of Medicine, Division of Gastroenterology and Hepatology, Mayo Clinic **RBX2660 Efficacy** Lindy Bancke, PharmD, Head of Clinical Development, Rebiotix Inc., a Ferring Company **RBX2660 Safety** Jonas Pettersson, MD, PhD, Senior Medical Director, Ferring Pharmaceuticals **Clinical Perspective** Colleen Kraft, MD, MSC, FIDSA, Associate Chief Medical Officer, Emory University Q & A – 30 Min
11:30 a.m. ET	**Break (10 min)**
11:40 a.m. ET	**FDA Presentations (90 min including Q&A)** **Rebyota (Fecal Microbiota, Live): Review of Efficacy and Safety (60 min)** • Omolara Adewuni, M.D. Medical Officer, Clinical Review Branch 2 Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER, FDA • Zhong Gao, Ph.D. Mathematical Statistician, Therapeutics Evaluation Branch 2 Division of Biostatistics (DB) Office of Biostatistics and Pharmacovigilance (OBPV), CBER, FDA Q & A – 30 min

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1:10 p.m. ET	**Lunch (40 min)**
1:50 p.m. ET	**Open Public Hearing (60 min)**
2:50 p.m. ET	**Break (10 Min)**
3:00 p.m. ET	**Committee Discussion and Voting (120 min)**
5:00 p.m. ET	**Meeting Adjourned – DFO**