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

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